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**Irish Society  
for Rheumatology**

**Autumn Meeting 2019**



**26-27 September 2019  
Killashee Hotel  
Naas, Co Kildare**





AN ORAL JAK INHIBITOR  
FOR THE TREATMENT  
OF RA & PsA<sup>1</sup>

# RAPID AND SUSTAINED EFFICACY<sup>2-8</sup>

## A MARK OF XELJANZ<sup>9</sup>

WHEN csDMARDs ARE NOT ENOUGH: PRESCRIBE XELJANZ<sup>1,9,10</sup>

**XELJANZ**<sup>®</sup>  
(tofacitinib citrate)

**SMALL PILL. BIG IMPACT.**<sup>2-4,11</sup>

### XELJANZ<sup>®</sup> ▼ (tofacitinib) Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing XELJANZ 5 mg or 10 mg film-coated tablets. **Presentation:** Film-coated tablet containing tofacitinib citrate, equivalent to 5 mg or 10 mg tofacitinib. **Indications:** in combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. Can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. In combination with MTX for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. **Dosage:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Tofacitinib is given with or without food. **RA and PsA:** The recommended dose is 5 mg administered orally twice daily. **UC:** The recommended dose is 10 mg given orally twice daily, for induction for 8 weeks and 5 mg given twice daily for maintenance. For patients who do not achieve adequate therapeutic benefit by week 8, the induction dose of 10 mg twice daily can be extended for an additional 8 weeks (16 weeks total), followed by 5 mg twice daily for maintenance. Tofacitinib induction therapy should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16. For some patients, such as those who have failed prior tumour necrosis factor (TNF) antagonist therapy, consideration should be given to continuation of the 10 mg twice daily dose for maintenance in order to maintain therapeutic benefit (see SmPC section 5.1). Patients who experience a decrease in response on tofacitinib 5 mg twice daily maintenance therapy may benefit from an increase to tofacitinib 10 mg administered twice daily. It is recommended not to initiate dosing in patients with an absolute lymphocyte count (ALC) less than  $0.75 \times 10^9/l$ , an absolute neutrophil count (ANC) less than  $1 \times 10^9/l$  or in patients with haemoglobin less than 9 g/dL. **Renal impairment:** No dose adjustment is required in patients with mild or moderate renal impairment. Patients with severe renal impairment the dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal renal function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal renal function is 10 mg twice daily. Patients with severe renal impairment should remain on a reduced dose even after haemodialysis. **Hepatic impairment:** No dose adjustment is required in patients with mild hepatic impairment. Patients with moderate hepatic impairment dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal hepatic function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal hepatic function is 10 mg twice daily. Tofacitinib should not be used in patients with severe hepatic impairment. **Elderly:** No dose adjustment is required in patients aged 65 years and older. Use with caution as increase risk and severity of adverse events. **Drug-drug Interactions:** Tofacitinib total daily dose should be reduced by half in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g.,

ketconazole) and inpatients receiving 1 or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole). Coadministration of XELJANZ with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response. Coadministration of potent inducers of CYP3A4 with XELJANZ is not recommended. **Contraindications:** Hypersensitivity to any of the ingredients, active tuberculosis (TB), serious infections such as sepsis, or opportunistic infections; severe hepatic impairment, pregnancy and lactation. Tofacitinib 10 mg twice daily is contraindicated in patients who have one or more of the following conditions: use of combined hormonal contraceptives or hormone replacement therapy, heart failure, previous venous thromboembolism, either deep venous thromboembolism or pulmonary embolism, inherited coagulation disorder, malignancy, or patients undergoing major surgery. **Warnings and Precautions:** Tofacitinib should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Patients treated with tofacitinib should be given a patient alert card. There was a higher incidence of adverse events for the combination of tofacitinib with MTX versus tofacitinib as monotherapy in RA clinical studies. Tofacitinib should be avoided in combination with biologics and potent immunosuppressants such as azathioprine, 6-mercaptopurine, ciclosporine and tacrolimus. **Infections:** Serious and sometimes fatal infections have been reported in patients administered tofacitinib. Rheumatoid arthritis patients taking corticosteroids may be predisposed to infection. Patients should be closely monitored for infections, with prompt diagnosis and treatment. Treatment should be interrupted if a serious infection develops. Use carefully in elderly or patients predisposed to, or with a history of infection (e.g. diabetes). **Tuberculosis:** Patients should be evaluated for both active and latent TB prior to being treated with tofacitinib, patients who test positive for latent TB should be treated with standard antimycobacterial therapy before administering tofacitinib. **Viral Reactivation:** In clinical studies viral reactivation and cases of herpes zoster have been observed. Screening for viral hepatitis should be performed in accordance with clinical guidelines prior to starting therapy with tofacitinib. The impact on chronic viral hepatitis is not known. **Vaccinations:** Prior to initiating tofacitinib, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Live vaccines should not be given concurrently with tofacitinib. **Malignancy:** Lymphomas and other malignancies have been observed in patients treated with tofacitinib. Patients with highly active disease may be at higher risk than the general population. The effect of tofacitinib on the development and course of malignancies is not known. NMSCs have been reported, the risk of NMSC may be higher in patients treated with tofacitinib 10 mg twice daily than in patients treated with 5 mg twice daily. Periodic skin examination is recommended in patients at increased risk. **Pulmonary embolism:** Pulmonary embolism has been observed in patients taking tofacitinib in clinical trials and post marketing reports. Tofacitinib 10 mg twice daily is contraindicated in patients who are at high risk for pulmonary embolism (see also SmPC section 4.3). Additional risk factors that should be considered in determining the patient's risk for PE are older age, obesity, smoking status, and immobilisation. **Interstitial lung**

**disease:** Caution is recommended in patients with a history of chronic lung disease as they may be more prone to infection. Asian patients are known to be at higher risk of ILD caution should be exercised with these patients. **Gastrointestinal perforations:** Tofacitinib should be used with caution in patients who may be at increased risk e.g. diverticulitis or concomitant use of corticosteroids or NSAIDs. **Cardiovascular risk:** Risk factors should be managed as part of usual standard of care. **Hypersensitivity:** Cases of drug hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately. **Laboratory Parameters:** Increased incidence of lymphopenia and neutropenia have been reported and decreases in haemoglobin and should be monitored in accordance with the SmPC. Monitor ANC and haemoglobin at baseline, 4-8 weeks and 3 monthly. ALC at baseline and 3 monthly. Tofacitinib has been associated with increases in lipid parameters maximal effects are observed at 6 weeks. Monitoring should be performed 8 weeks after initiation and managed according to hyperlipidemia guidelines. Increases in liver enzymes greater than 3x ULN were uncommonly reported, use caution when initiating with potential hepatotoxic medicinal products. **Pregnancy & Lactation:** Use of tofacitinib during pregnancy and breast-feeding is contraindicated. **Side Effects:** The most common serious adverse reactions were serious infections; pneumonia, cellulitis, herpes zoster, UTIs, diverticulitis, appendicitis and opportunistic infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension. The most commonly reported adverse reactions in patients receiving tofacitinib 10 mg twice daily in the induction studies were headache, nasopharyngitis, nausea, and arthralgia. Commonly reported adverse reactions ( $\geq 1/100$  to  $< 1/10$ ), were pneumonia, influenza, herpes zoster, urinary tract infection, sinusitis, bronchitis, nasopharyngitis, pharyngitis, anaemia, headache, hypertension, cough, abdominal pain, vomiting, diarrhoea, nausea, gastritis, dyspepsia, rash, arthralgia, pyrexia, oedema peripheral, fatigue, blood creatine phosphokinase increased. Refer to section 4.8 of the SmPC for further information on side effects, including description of selected adverse reactions. **Legal Category:** S1A. **Marketing Authorisation Number:** EU/1/17/1178/003 - 5 mg (56 film-coated tablets); EU/1/17/1178/007 - 10 mg (56 film-coated tablets). **Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 263 or at EU.MEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 3531 4676500.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Last revised: 06/2019.

Ref: XJ 7.1.

#### References:

1. XELJANZ Summary of Product Characteristics. 2. van Vollenhoven RF et al. *N Engl J Med* 2012; 367: 508-519. 3. van der Heijde D et al. *Arthritis Rheum* 2013; 65: 559-570. 4. Fleischmann R et al. *N Engl J Med* 2012; 367: 495-507. 5. Strand V et al. *Ann Rheum Dis* 2017; 76: 1335. 6. Wollenhaupt J et al. Poster presented at: American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting; November 3-8, 2017; San Diego, CA, USA. 7. Mease P et al. *N Engl J Med* 2017; 377: 1573-1580. 8. Gladman D et al. *N Engl J Med* 2017; 377: 1525-1536. 9. Smolen JS et al. *Ann Rheum Dis* 2017 Mar 6. [Epub ahead of print]. 10. Singh JA et al. *Arthritis Rheumatol* 2016; 68: 1-26. 11. Burmester GR et al. *Lancet* 2013; 381(9865): 451-460.

PP-XEL-IRL-0454 | Date of preparation: July 2019

RA=rheumatoid arthritis, PsA=psoriatic arthritis, csDMARD=conventional synthetic DMARD





## Welcome Message from the ISR President Dr Sinéad Harney



### Dear Colleagues and Friends

It gives me great pleasure to welcome you to Killashee House Hotel for the 2019 ISR Autumn meeting. I Hope you will enjoy the meeting and of course the social aspect too. I am very grateful to Dr John Ryan, Dr Grainne Murphy and Prof Ursula Fearon who along with myself put together what we hope will be a varied and interesting programme.

We are covering basic science with Prof Aisling Dunne and look forward to her talk. A holistic approach to aspects of care is at the core of this meeting with Prof David Walsh speaking on pain, Dr Natasha Jordan speaking on fatigue in lupus and Dr Marwan Bukhari speaking on quality of life issues in osteoporosis.

Mental health issues in health professionals is important and I look forward to Dr Mark Rowe's talk which should be enlightening.

We would like to thank our guest speakers for taking the time to travel here to deliver their lectures. We would like to thank all of our scientific and clinical presenters.

I would also like to invite everyone to attend the early morning meeting on private practice. As always Michael Dineen, Marie Caston and colleagues have worked tirelessly behind the scenes to organise this meeting – we thank them for that.

We also extend our gratitude to all of our colleagues who corrected abstracts, grants and submissions for this meetings.

Lastly, I would like to thank our colleagues in the pharmaceutical industry who continue to support the ISR and individual departments around Ireland.

In my continued role as ISR President my main aim is to keep our speciality relevant within the HSE and government and also to re-emphasise some of the complexities of conditions we treat which may get overlooked. We have introduced the hub prescribing with some hitches and look forward to the gainshare being used sensibly and by the Rheumatology departments throughout the country.

I would like to highlight my thanks to the patients who did the Dublin mini-marathon and would encourage all departments to highlight the importance of exercise to our patients.

The multi-disciplinary nature of our speciality means that our close relationships with nursing, physiotherapy and occupational therapy, which have been developed over many years, should be a model for the HSE to embrace meaningfully and support properly which hasn't always happened.

Lastly, the lack of proper infrastructure within many departments and the shortage of staff needs to be highlighted continuously.

Enjoy the meeting

**Dr Sinéad Harney**  
President ISR



*Celebrating*  
**22 YEARS\***  
*in*  
**RHEUMATOLOGY<sup>1,2\*\*</sup>**

*\*\*includes clinical development*

# A future built on *experience*

Further information is available upon request from Abbvie Limited,  
 14 Riverwalk, Citywest Business Campus, D24 XN32  
 Full prescribing information is available at [www.medicines.ie](http://www.medicines.ie)  
 Legal Category: POM

- References**
- <sup>1</sup> Humira Summary of Product Characteristics, available at [www.medicines.ie](http://www.medicines.ie)
  - <sup>2</sup> Burmester GR, Mease P, Dijkmans BAC et al. Adalimumab safety and mortality rates from global clinical trials of six immune-mediated inflammatory diseases. *Ann Rheum Dis* 2009; 68(12): 1863-1869

Date of preparation: July 2019  
 IE-HUM-190031



**HUMIRA<sup>®</sup>**  
 adalimumab  
*destination you<sup>™</sup>*



## ISR Autumn Meeting 26-27 September, Killashee Hotel, Co. Kildare Programme

### Thursday, 26 September

- 08.00-09.30 Registration
- 08.30-09.30 CAG Meeting for Consultant Members
- 09.30 Welcome Address by ISR President:  
Dr Sinead Harney
- 09.35-10.15 Prof Aisling Dunne  
Molecular Immunology Group Lead,  
Trinity College Dublin, the University  
of Dublin.  
*'Disease-associated particulates and  
joint inflammation'*
- 10.15-10.55 Oral Abstract 1 – 4 (Clinical)
- 10.55-11.30 Coffee,  
Poster Viewing and Visit the Industry
- 11.30-12.00 RPIF Winners 2018 Presentations  
(6 x 5 mins presentations)
- 12.00-12.40 Prof Robert Moots  
Dept of Musculoskeletal Biology,  
Institute of Ageing and Chronic Disease  
University of Liverpool.  
*'Clinical update on the management  
of Behçet's'*
- 12.40-13.00 Young Investigator Award  
Top Abstract Submission as decided by  
the Abstract Review Panel.
- 13.00-14.00 Lunch and Visit the Industry
- 14.00-14.30 Poster Round – Top 10 Posters  
(Selected by Review Panel)
- 14.30-15.10 Dr Natasha Jordan,  
Consultant Rheumatologist  
Addenbrooke's Hospital, Cambridge, UK  
*'Fatigue in Lupus'*
- 15.10-15.50 Oral Abstracts 5 – 8 (Scientific)

- 15.50-16.15 Coffee,  
Poster Viewing and Visit the Industry
- 16.15-17.15 Rheumatology Round Table  
*'Conundrums in Rheumatology'*
- 17.15 AGM
- 18.00 AbbVie Satellite Meeting
- 20.00 Conference Dinner

### Friday, 27 September

- 08.00-09.30 Sp R Study Group
- 08.00-09.30 Private Practice Meeting
- 09.30-10.30 4 Clinical Cases
- 10.30-11.10 Dr Marwan Bukhari  
Consultant Rheumatologist  
Clinical lead for rheumatology at the  
University Hospitals of Morecambe  
Bay NHS, UK  
*'Quality of Life issues with Osteoporosis'*
- 11.10-11.40 Coffee,  
Poster Viewing and Visit the Industry
- 11.40-12.15 Dr Mark Rowe  
Specialist in Positive Health and Lifestyle  
Waterford Health Park.  
*'Live with Vitality'*
- 12.15-12.30 Bernard Connor Medal Winner
- 12.30-13.10 Prof David Walsh  
Director, Arthritis Research UK Pain Centre,  
Faculty of Medicine & Health Sciences.  
Nottingham City Hospital. UK  
*'The pain of rheumatic disease'*
- 13.10 Award Ceremony

# FOR RA PATIENTS WITH POOR PROGNOSTIC FACTORS, TIME IS OF THE ESSENCE<sup>1-4</sup>



RA patients with high disease activity, including ACPA/RF seropositive patients, are likely to have significantly worse and faster disease course vs seronegative, and must be identified as soon as possible<sup>1-4</sup>

Early treatment with ORENCIA® helps prevent irreversible radiographic progression<sup>5</sup>

ORENCIA® is even more effective in ACPA seropositive patients than seronegative patients (DAS28 and HAQ DI, Post-Hoc Analyses)<sup>6</sup>

Your at-risk patients may stay the course with ORENCIA® due to low rates of drug-related discontinuations<sup>5,7</sup>

ORENCIA®(abatacept)  
**CLICKJECT®**  
PRE-FILLED PEN

A convenient option for patients who choose self-injection<sup>7</sup>



Don't wait until it's too late; RA patients with poor prognosis require your attention to prevent their disease from progressing<sup>1-4</sup>

ORENCIA, in combination with methotrexate, is indicated for:

- The treatment of moderate to severe active RA in adult patients who responded inadequately to previous therapy with one or more DMARDs including MTX or a TNF-alpha inhibitor
- The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with MTX

August 2019 427UK1900890-01

Bristol-Myers Squibb

## ORENCIA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing and for full information on the medicinal product

**PRESENTATION:** 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial; each ml contains 25 mg of abatacept, after reconstitution. 125 mg pre-filled syringe and Clickject pre-filled pen, for SC injection; each pre-filled syringe and pen contains 125 mg of abatacept in 1 ml.

**INDICATION:** Rheumatoid arthritis (RA) (IV infusion, SC pre-filled syringe and pen):

Orencia, in combination with methotrexate, is indicated for:

- The treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate or a tumour necrosis factor (TNF)-alpha inhibitor.
- The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.

A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate, see SmPC. **Psoriatic Arthritis ((PsA) IV infusion, SC pre-filled syringe and pen):** Orencia alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required. **Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV infusion only):** Orencia in combination with methotrexate is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. **DOSE:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA or PsA. **Orencia 250 mg powder for concentrate for solution for IV infusion Adults and elderly:** Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≤ 60 kg to ≥ 100 kg: 750 mg (3 vials). Patients weighing > 100kg: 1000 mg (4 vials). **Treatment of pJIA:** Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg. Paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orencia IV should be given at 2 and 4 weeks, then every 4 weeks thereafter. **Children:** Use in children below 6 years of age is not recommended. **Orencia 125 mg solution for injection (SC pre-filled syringe and pen) Adults and elderly:** Orencia SC may be initiated with or without an IV loading dose. Orencia SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 125 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injections. Patients transitioning from Orencia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. **Children:** The safety and efficacy of Orencia SC in children below

18 years of age have not been established. The continuation of treatment with abatacept should be re-assessed if patients do not respond within 6 months. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. **WARNINGS AND PRECAUTIONS:** **Allergic Reactions:** Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. Orencia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactoid reaction. **Infections:** Caution should be exercised when considering use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with Orencia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orencia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orencia. Co-administration of Orencia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orencia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. **Malignancies:** The potential role of Orencia in the development of malignancies is unknown. However periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. **Elderly:** Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. **Autoimmune processes:** Theoretical risk of deterioration in autoimmune disease. **Immunisation:** Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orencia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orencia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orencia in combination with sulfasalazine, hydroxychloroquine or leflunomide. **PREGNANCY AND LACTATION:** Abatacept may cross the placenta into the serum of infants born to women treated with abatacept during pregnancy. Consequently, these infants may be at increased risk of infection. Administration of live vaccines to infants exposed to abatacept in utero is not recommended for 14 weeks following the mother's last exposure to abatacept during pregnancy. Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In clinical trials and post-marketing experience, the following adverse drug reactions were reported. **Very Common (> 1/10):** upper respiratory tract infection including tracheitis, nasopharyngitis, sinusitis. **Common (> 1/100 to < 1/10):** Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), pneumonia, influenza, headache, dizziness, hypertension blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), fatigue, asthenia, local injection site reactions\*, systemic injection reactions\* (e.g. pruritus, throat tightness, dyspnea) **Uncommon (> 1/1,000 to < 1/100):**

Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, rhinitis, ear infection, basal cell carcinoma, skin papilloma, thrombocytopenia, leukopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, paraesthesia, conjunctivitis, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, blood pressure decreased, hot flush, flushing, vasculitis, chronic obstructive pulmonary disease exacerbated, bronchospasm, wheezing, dyspnea, throat tightness, gastritis, increased tendency to bruise, dry skin, alopecia, pruritus, urticaria, psoriasis, acne, erythema, hyperhidrosis, arthralgia, pain in extremity, amenorrhoea, menorrhagia, influenza like illness, weight increased. **Rare (> 1/10,000 to < 1/1,000):** Tuberculosis, bacteraemia, gastrointestinal infection, pelvic inflammatory disease, lymphoma, lung neoplasm malignant, squamous cell carcinoma. \*Orencia SC, see SmPC for information on other undesirable effects. **LEGAL CATEGORY:** POM **MARKETING AUTHORISATION NUMBER AND BASIC NHS PRICE [UK only]:** Orencia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack: £302.40 Orencia 125 mg solution for injection (pre-filled syringe)-EU/1/07/389/008 and Clickject pre-filled pen - EU/1/07/389/011, 4 pre-filled syringes with needle guard: £1209.60 4 pre-filled pens: £1209.60 **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK. Tel: 0800-731-1736 **LOCAL REPRESENTATIVE IN UK:** Bristol-Myers Squibb Pharmaceuticals Limited, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK. Tel: 0800-731-1736 **LOCAL REPRESENTATIVE IN IRELAND:** Bristol-Myers Squibb Pharmaceuticals UK, Plaza 254, Blanchardstown Corporate Park 2, Ballycoolin, Dublin, D15 T867, Ireland. Tel: 01 483 3625 **DATE OF LAST REVISION:** July 2017 **ADDITIONAL INFORMATION AVAILABLE ON REQUEST**

Adverse events should be reported. Reporting forms and information can be found at: UK - [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store; Ireland - Freeport HPRM Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (UK); 1 800 749 749 (Ireland).

**REFERENCES:** 1. Lamerato L et al. *J Med Econ* 2018;21(3):231-40. 2. Sokolove J et al. *Arthritis Rheumatol* 2014;66(4):813-21. 3. van der Helm-van Mil AHM et al. *Arthritis Res Ther* 2005;7(5):R949-R958. 4. National Institute for Health and Care Excellence. Rheumatoid arthritis in adults: management. NICE guideline. Published: 11 July 2018. Available at [nice.org.uk/guidance/ng100](http://nice.org.uk/guidance/ng100) (last accessed: February 2019). 5. Schiff M et al. *Ann Rheum Dis* 2014;73(1):86-94. 6. Sokolove J et al. *Ann Rheum Dis* 2016;75(4):709-14. 7. ORENCIA® SmPC. Available at [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) (last accessed: May 2019). **ABBREVIATIONS:** ACPA, anti-citrullinated protein antibody; DMARD, disease modifying anti-rheumatic drug; MTX, methotrexate; RA, rheumatoid arthritis; RF, rheumatoid factor; TNF, tumour necrosis factor. August 2019 427UK1900890-01



**Programme for IRHPS Autumn Meeting & AGM**  
**Killashee Hotel, Naas, Co. Kildare**

**Thursday 26th September 2019**

- 08.00 - 09.30      **Registration**
- 09.30 - 09.45      **IRHPS Welcome Address by Louise Murphy**  
**Bursary Officer, IRHPS**
- 09.45 - 10.30      ***The relationship between pain and sedentary behaviour in***  
***Rheumatoid Arthritis***  
**Karen Quinn,**  
Physiotherapy Department, Cork University Hospital
- 10.30 - 11.15      ***Factors affecting completion rates of physical activity interventions in***  
***people who have rheumatoid arthritis: a systematic review***  
**Dr. Louise Larkin,**  
School of Allied Health, Faculty of Education & Health Sciences,  
University of Limerick
- 11.15 - 11.45      Coffee and Poster Viewing
- 11.45 - 12.00      ***A Descriptive Account of the Practices of Rheumatology Nurses in the***  
***Provision of Telephone Helpline Services in the Republic of Ireland***  
**Helen Reynolds,**  
North Western Rheumatology Unit, Our Lady's  
Hospital, Manorhamilton, Co. Leitrim
- 12.00 - 12.30      ***'Arthritis Ireland's Strategic Plan 2019-2023'***  
**Gráinne O'Leary,**  
Chief Executive Arthritis Ireland
- 12.30 - 13.30      Lunch / Poster viewing / Meet the industry
- 13.30 - 14.30      ***'Using technology to support clinical care and research in rheumatology'***  
**Professor Will Dixon.**  
Director of the Arthritis Research UK Centre of Epidemiology,  
Medical Director of Greater Manchester Connected Health Cities,  
Honorary Consultant Rheumatologist, Salford NHS
- 14.30 - 15.10      ***Plenary session: ISR programme 'Fatigue in Lupus'***  
**Dr Natasha Jordan,**  
Consultant Rheumatologist, Addenbrooke's Hospital, Cambridge
- 15.10 - 16.00      **ISR Programme**
- 16.00                **IRHPS AGM**
- 20.00                **Gala Dinner**

# When life is too busy for RA

Given a choice, 53% of RA patients would chose a monthly regime<sup>1\*</sup>



## GO further with Simponi

With Simponi, approximately 70% of patients remained on treatment after 5 years.<sup>2</sup> Make your 1st choice count.



### SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)

**ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre filled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **INDICATIONS** *Rheumatoid Arthritis (RA)*: Simponi, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA)*: Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS)*: Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA)*: Simponi is indicated for the treatment of severe, active nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. *Ulcerative colitis (UC)*: Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Polyarticular juvenile idiopathic arthritis (pJIA)*: Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **DOSE AND ADMINISTRATION** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA, UC or pJIA. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. **RA**: Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. **PsA**: Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. **AS and nr-Axial SpA**: Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. **UC**: *Patients weighing < 80 kg*: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2. Patients who have an adequate response should receive 50 mg at week 6 and every 4 weeks thereafter. Patients who have an inadequate response may benefit from continuing with 100 mg at week 6 and every 4 weeks thereafter. *Patients weighing ≥ 80 kg*: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). **pJIA**: Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3-4 doses). **Missed dose**: If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. **Elderly patients (> 65 years)**: no dose adjustment required. **Paediatric patients (<18 years)**: For indications other than pJIA, Simponi is not recommended. **Patients with renal and hepatic impairment**: Simponi is not recommended. **CONTRAINDICATIONS** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS AND WARNINGS** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Reminder Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. **Hepatitis B (HBV) reactivation**: Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi. **Malignancies and lymphoproliferative disorders**: Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6 mercaptopurine (6-MP). The potential risk with the combination of AZA or 6 MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma and Merkel cell carcinoma (all TNF-blocking agents including Simponi) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer.

**Heart Failure**: Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. **Neurological events**: Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery**: Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes**: If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions**: There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers, including Simponi. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents**: It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions**: If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations**: **Elderly patients (> 65 years)**: Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. **Paediatric patients (<18 years)**: **Vaccinations**: it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. **Excipients**: Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **INTERACTIONS** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **PREGNANCY AND LACTATION** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **SIDE EFFECTS Refer to SmPC for complete information on side effects** **Very Common (≥ 1/10)**: upper respiratory tract infection; **Common (≥ 1/100)**: bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, Leukopenia (including neutropenia), anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, hepatosplenic T-cell lymphoma\*, leukopenia, thrombocytopenia, pancytopenia, aplastic anaemia, agranulocytosis, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. \*Observed with other TNF-blocking agents. **Paediatric population**: pJIA: The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection **Legal Category**: Prescription Only Medicine. **Marketing Authorisation Number** 50 mg Pre-filled Pen EU/1/09/546/001 50 mg Pre-filled Syringe EU/1/09/546/003 100 mg Pre-filled Pen EU/1/09/546/005 **Marketing Authorisation Holder** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands **Date of Revision of Text**: September 2018 **Simponi**/PI-IRE/09-18 © Merck Sharp & Dohme Ireland (Human Health) Limited 2018. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to MSD (Tel: 01-2998700) **Date of preparation**: March 2019

Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to MSD (Tel: 01-2998700)

**References**: 1. Huynh, T.K. et al. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. Patient Preference and Adherence, 2014; 8: 93-99. 2. Keystone EC, Genovese MC, Hall S et al. Safety and efficacy of subcutaneous golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: final 5-year results of the GO-FORWARD trial. J Rheumatol. 2016;43:298-306. \*Rheumatoid arthritis patients preferring subcutaneous therapies



Red Oak North, South County Business Park,  
Leopardstown, Dublin D18 X5K7 Ireland

monthly  
**Simponi**<sup>®</sup>  
golimumab



## Biographical Sketches

### Speakers

#### Prof Aisling Dunne

Molecular Immunology Group Lead,  
Trinity College Dublin, the University  
of Dublin.



Professor Dunne is a lecturer, principal investigator and Director of Undergraduate Teaching and Learning with the School of Biochemistry and Immunology, Trinity College Dublin. Her work to date has focused on endogenous damage-associated molecular patterns (DAMPs) that are associated with sterile inflammatory diseases such as osteoarthritis (OA). For example, her group is currently exploring the signalling events triggered by DAMPs in macrophages and synovial fibroblasts and have identified a number of molecules and pathways activated by OA-associated calcium phosphate crystals. She was also recently named as a funded investigator with the SFI centre, AMBER (Advanced Materials and BioEngineering Research) and is working with the Trinity Centre for Bioengineering to assess the impact of traditional and novel biomaterials on the host immune system, stem cell differentiation and tissue regeneration. Her group is currently funded by Science Foundation Ireland and the Health Research Board, Ireland.

#### Prof Robert Moots

Dept of Musculoskeletal Biology,  
Institute of Ageing and Chronic Disease  
University of Liverpool.



Robert Moots is Professor of Rheumatology at the University of Liverpool. Qualifying in Medicine in London, he earned his PhD in immunology at the University of Oxford UK and worked at Harvard Medical School before returning to the UK to establish a new rheumatology group in Liverpool.

His research focuses on inflammatory diseases, from bench to bedside, he has published extensively and his group is designated European (EULAR) Centre of Excellence for Rheumatology research. Robert advises NICE (and chaired the panel that devised quality standards for RA), is Past Editor of Rheumatology and lectures all around the world on his work. Clinical service is a crucial part of his role - he has extensive experience in managing hard-to-treat rheumatological diseases and in delivering therapy with both standard and high cost drugs, with referrals from around the UK and internationally. Robert is Director of the national Centre of Excellence for Behçet's syndrome in Liverpool. He should learn to say "no" more often, according to his wife.

#### Dr Natasha Jordan

Consultant Rheumatologist  
Addenbrooke's Hospital, Cambridge, UK



Dr Natasha Jordan is a Consultant Rheumatologist at Addenbrooke's hospital, Cambridge. Her major clinical and research interests are autoimmune connective tissue diseases and systemic vasculitis. She is Co-Director of the Cambridge Rheumatology Clinical Trials Unit and a member of the BILAG group. Dr. Jordan studied Medicine at University College Dublin followed by higher specialist training in General Internal Medicine and Rheumatology. She subsequently worked for 5 years at the Louise Coote Lupus Unit, St Thomas' Hospital, London, initially as a clinical research fellow and then as an honorary consultant. She has been the recipient of an Arthritis Research UK Fellowship and the Graham Hughes Clinical Research Fellowship allowing her to undertake research in the areas of SLE and vasculitis. She obtained her PhD from King's College London investigating the genetics of lupus nephritis.

#### Dr Mark Rowe

Specialist in Positive Health and Lifestyle  
Waterford Health Park.



Dr. Mark Rowe has been a practicing family physician for over 20 years, having graduated from Medical School (UCD Dublin, Ireland) in 1991. He is the founder of the Waterford Health Park, which has become both the base for Dr. Rowe's medical practice as well as the 'Lifestyle Medicine Be Well Clinic'.

Dr. Rowe is the author of two books - 'A Prescription for Happiness: The Ten Commitments to a Happier, Healthier Life' and 'The Men's Health Book'. Mark is also a regular contributor for a number of publications including the Farmer's Journal, where he shares his thoughts on positive health and wellbeing practices.

As a Keynote speaker, Mark Rowe regularly delivers events and workshops for organisations around the world. His TEDx talk titled 'The Doctor of the Future: Prescribing Lifestyle as Medicine' took place in University College Dublin in 2017. Notable engagements to date have included Smurfit Executive Leadership Program, the American House of Representatives and a number of Fortune 500 companies.

Dr. Mark Rowe is among the first medical professionals globally to be certified as a Diplomate of the International Board of Lifestyle Medicine. Lifestyle Medicine is defined as an evidence-based 'lifestyle first' approach to prevention and treatment of chronic disease. Mark Rowe has always held a strong desire to change the culture of 'a pill for every ill'. Instead he advocates lifestyle change as the best medicine for lasting wellbeing.



**Dr Marwan Bukhari**

Consultant Rheumatologist  
Clinical lead for rheumatology at the  
University Hospitals of Morecambe  
Bay NHS, UK



Marwan Bukhari is a consultant rheumatologist and clinical lead for rheumatology at the University Hospitals of Morecambe Bay NHS foundation Trust and an honorary senior lecturer at Manchester university. Dr Bukhari trained in rheumatology and epidemiology in Manchester. His research interests include inflammatory arthritis, quality of life in patients with arthritis and the epidemiology of osteoporosis. Dr Bukhari is educational lead for medicine for students at Lancaster University and associate director for medical education at the Royal Lancaster infirmary. He is also the co-editor of the journal Rheumatology. He is the northern regional advisor for National Rheumatoid arthritis society.

**Prof David Walsh**

Director, Arthritis Research UK Pain Centre,  
Faculty of Medicine & Health Sciences.  
Nottingham City Hospital. UK



David Walsh is Professor of Rheumatology at the University of Nottingham and Consultant Rheumatologist at Sherwood Forest Hospitals NHS Foundation Trust. In 2010 he established the Arthritis Research UK Pain Centre in Nottingham, together with a multidisciplinary research team which includes preclinical neurosciences, psychology, neuroimaging, orthopaedics, genetics, epidemiology and evidence synthesis. The Centre aims to develop new and improved treatments through a translational research programme into the mechanisms by which changes within the joint and in the nervous system interact with psychosocial factors to produce arthritis pain. His preclinical research has focused on structural changes that contribute to joint pain, in particular angiogenesis, nerve growth, inflammation and subchondral bone turnover. His clinical research is defining the spectrum of pain phenotypes in people with arthritis based on underlying pain mechanisms, in order to better target treatments to those most likely to benefit. In 2017 he became the first lead for the Musculoskeletal Theme at the launch of the NIHR Nottingham Biomedical Research Centre and represents Nottingham on the NIHR musculoskeletal Translational Research Collaboration. He was a member of the Guideline Development Group for NICE guidelines on the management of low back pain and sciatica, and continues clinical practice in rheumatology.

**ISR Board members**

**Dr Sinéad Harney**  
President



Dr Sinéad Harney graduated from UCC in 1994 and did her specialist training in Rheumatology and General Medicine in Dublin. She completed her training in Oxford in 2005 and was awarded a DPhil by thesis titled "Major Histocompatibility Genetics of Rheumatoid Arthritis". She was appointed to a Consultant Rheumatologist post in Cork University Hospital in 2005 and has worked there since. She completed a Masters in Sports and Exercise Medicine in UCC in 2007. Her research interests include – Genetics of inflammatory arthritis and occult cardiovascular disease in Rheumatoid Arthritis and she has over 90 publications. She is currently the treasurer of the Irish Society of Rheumatology and a board member of the TUE committee of the Irish Sports Council.

**Dr Clare Matthews**  
Honorary Secretary



Consultant Rheumatologist, Ulster Hospital, Belfast Dr Clare Matthews graduated from Queens University Belfast in 1994. She completed registrar training with CCT in Rheumatology and general medicine in 2007. She completed an MD "Clinical, genetic and immunohistochemical findings of early inflammatory arthritis" from The Queen's University, Belfast in 2004. She trained in Belfast with a period of training in St Vincent's University Hospital Dublin through her research interest in synovial disease. Dr Matthews was first appointed as a consultant in Belfast City Hospital and moved to her current post in The South Eastern Trust in 2009.

**Dr John Ryan**  
Honorary Treasurer



Dr John Ryan is a graduate of the Royal College of Surgeons in Ireland, he completed his higher medical training in rheumatology and general internal medicine in Ireland. He undertook a fellowship at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in Bethesda, Maryland. During this time he undertook translational research into disordered innate immunity manifesting as recurrent fever syndromes. He joined Dr Sinead Harney in the Rheumatology service at Cork University Hospital in 2010. The Rheumatology department has since expanded to include Dr Grainne Murphy. In July 2017 he took up the post of National Specialty Director for Rheumatology.



**Dr Shawn Chavrimootoo**

Shawn Chavrimootoo is a Consultant Rheumatologist at Our Lady's Hospital, Navan, Co. Meath. He graduated in Medicine from RCSI, Dublin in 2002 and developed an interest in Rheumatology during his Senior House Officer years in Connolly Hospital, Blanchardstown. Following this, he completed higher specialist training in Cork University Hospital, Kerry General Hospital, Connolly Hospital and St Vincent's University Hospital in Dublin. He was appointed to his Consultant Rheumatologist post in 2013 when he joined Dr Ramakrishnan at Our Lady's Hospital, Navan, from where they currently provide a regional Rheumatology service for the North East of Ireland. His clinical interests include osteoporosis as well as gout, inflammatory arthritis, spondyloarthritis, connective tissue disease and vasculitis.



**Prof. Suzanne Donnelly**

Associate Professor Suzanne Donnelly is a consultant rheumatologist at the Mater Misericordiae University Hospital Dublin & Associate Dean (Education) in UCD School of Medicine. She is a graduate of Trinity College Dublin and trained in Dublin and Oxford before being appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. Her clinical interests include systemic autoimmune disease, Systemic Lupus Erythematosus and pregnancy in the rheumatic diseases. Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London. She joined UCD as Director of Clinical Education in 2008, and was appointed Associate Dean, UCD School of Medicine in 2017. In partnership with Arthritis Ireland, she initiated a patient educator programme to enhance medical students' education in rheumatological disease. The programme has enabled over 2000 medical students to meet patients with arthritis first hand. Suzanne is rheumatology author for the medical textbook *Medicine at A Glance* and a contributing author to *The Rheumatology Handbook*. She was ISR nominee to the board of Arthritis Ireland (2008-13), a board member of Raynauds and Scleroderma Ireland (2007-10) and medical patron of Lupus Group Ireland.



**Professor Ursula Fearon**

Professor Ursula Fearon is head of Molecular Rheumatology, School of Medicine, Trinity Biomedical Sciences Institute, Trinity College Dublin. Professor Fearon's research is a bench-to-beside translational approach, focusing on understanding the underlying mechanisms that drive disease pathogenesis; her team specifically examine components of joint inflammation at a cellular and molecular level to dissect out the signalling and gene pathways that are involved in the pathogenesis of inflammatory arthritis and rheumatic diseases. She has established strong collaborative research networks across



Europe, USA and Singapore. Professor Fearon, has been awarded significant research funding from Arthritis-Ireland, Health Research Board, Science Foundation Ireland, IRCSET, European-ASPIRE, JU Innovative Medicines Initiative (IMI) and Maeve Binchy Funding for Arthritis Research, in addition to industry collaborative partnerships. She has published extensively in high impact peer-reviewed journals, and her research has been awarded several National/International awards.

**Dr Orla Killeen**

Dr Orla Killeen qualified from UCG (NUI) Galway in 1996. She trained in General Paediatrics in Our Lady's Hospital for Sick Children, Crumlin and in Temple Street University Hospital, Dublin before sub-specialising in Paediatric Rheumatology. She undertook her paediatric rheumatology training at Great Ormond Street Children's Hospital, London and went on to complete a Barbara Ansell Fellowship in Paediatric Rheumatology in the Royal Hospital for Sick Children, Glasgow. She was appointed as Ireland's first Paediatric Rheumatologist in 2004, and is based at Our Lady's Children's Hospital, Crumlin and St Vincent's University Hospital, Dublin since July 2006. She is the Clinical lead for the National Centre for Paediatric Rheumatology (NCP), providing care for patients both on a local and national level up to 18 years of age. Her areas of interest include Adolescent Rheumatology Transition Care as well as JIA, Down's arthropathy and Auto-Inflammatory syndromes.



**Dr Bernadette Lynch**

Dr Bernadette Lynch graduated from the Royal College of Surgeons in Ireland in 2003. She completed her higher specialist training in Rheumatology and General Medicine in 2013 having worked and studied in Dublin, Galway and London. She was awarded an MD from University College Dublin in 2011 for work on IL-22 and musculoskeletal ultrasound in Inflammatory Arthritis. She undertook a fellowship in Scleroderma and Vasculitis at the Royal Free Hospital Hampstead under Professor Chris Denton and Dr Aine Burns. During this time, Bernadette was part of the UK Scleroderma Study Group (UKSSG) which developed the national guidelines on the management of complications of Scleroderma. She took up her current appointment as Consultant Rheumatologist and General Physician in University Hospital Galway in 2015. Her principal clinical and academic interests are Scleroderma and Inflammatory Arthritis.





**Dr Adrian Pendleton**

Consultant Rheumatologist  
Musgrave Park Hospital, Belfast



Dr Adrian Pendleton is a Consultant Rheumatologist and Clinical Lead for Rheumatology in the Belfast Health and Social Care Trust. Dr Adrian Pendleton trained in both Rheumatology and General Internal Medicine in Belfast and Nottingham. He was first appointed as a consultant Rheumatologist at the Queens Medical Centre, Nottingham University Hospitals before returning to the Belfast Trust Health and Social care Trust. Dr Pendleton is a Fellow of the Royal College of Physicians of Edinburgh and a Fellow of the Royal College of Physicians of Ireland and a Fellow of the British Society for Sport and Exercise Medicine (BASM). He is currently the Regional Specialty Advisor for Rheumatology with the Joint Royal College Physicians Training Board. Dr Pendleton has many research interests which include Early diagnosis and management of inflammatory arthritis, use of musculoskeletal ultrasound in Inflammatory arthritis, vasculitis and soft tissue injury.

**Dr Bryan Whelan**

Dr Bryan Whelan is a Consultant Rheumatologist in Our Lady's Hospital in Manorhilton, Co Leitrim and an Honourary Senior Lecturer in Medicine in NUIG. He qualified from UCD in 2000 and completed BST in the Mater Hospital in Dublin. He completed SpR training in Rheumatology in CUH, the Mater Hospital and University College London. He has an MD and Masters Sports and Exercise Medicine from UCC and an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine. He is currently a board member of Arthritis Ireland, the SUH Research and Education Foundation, a member of the Academic Committee of the FSEM and a member of the Advisory Committee for Human Medicines Clinical Trials Subcommittee of the HPRA. His current research interests include muscle disease, exercise in rheumatology and osteoarthritis.



**Professor Geraldine McCarthy**

Geraldine McCarthy graduated in Medicine from NUI. She received her Fellowship in Rheumatology at the Medical College of Wisconsin. Her research has focused on the biological effects of calcium-containing crystals in degenerative joint disease as well as in atherosclerosis and breast cancer. Promoted to Associate Professor of Medicine at the Medical College of Wisconsin in 1996 where she remained until her return to Dublin.



Prof McCarthy was appointed Consultant in Rheumatology at the MMUH and Cappagh National Orthopedic Hospital Dublin in 1999 where she continues to run a busy clinical practice. She teaches as part of the University College Dublin Faculty of Medicine where she was the first clinician to be

appointed Full Clinical Professor of Medicine through the Clinical Pathways in 2009.

Geraldine has current international collaborations in the UK, USA, Europe, Australia, New Zealand and Canada, particularly in relation to calcium crystal deposition diseases as well as gout. She continues her involvement in bench research related to the pathogenesis of basic calcium phosphate crystal-induced joint disease and participates in and contributes to numerous international collaborations related to gout. Other research interests include platelet activation in inflammatory arthritis and its role in enhanced cardiovascular risk. She also participates in collaborative studies of the pathogenesis of giant cell arteritis and HIV-associated bone pathology.

Author of over 130 publications, including original manuscripts, editorials, reviews and book chapters and has spoken at many national and international meetings. She has been winner of several research and teaching awards and has mentored many medicine and science graduates in clinical practice and in research.

**Dr Colm Kirby**

Colm graduated with a degree in medicine from UCC in 2011. Following completion of CUH medical BST I commenced the Rheumatology HST in 2016. After spending some time University College Hospital Galway and Cork University Hospital, he now works in Tallaght University Hospital. Special interests include Musculoskeletal Ultrasound and premature atherosclerosis associated with systemic inflammatory diseases.



Dr Anne Barbara Mongey raising a point



Photos from ISR Spring Meeting 2019



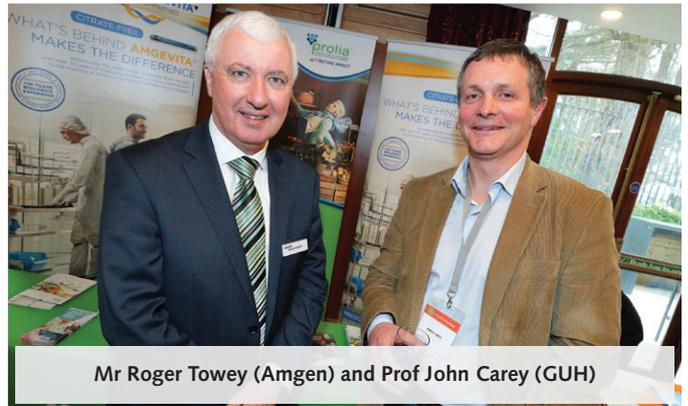
Prof Geraldine McCarthy; Professor David Kane;  
Dr Maurice Barry and Dr Carl Orr



Networking at breaktime



Dr Ruth Lee (Bon Secours, Dublin); Dr Maha Azeez and  
Dr Donough Howard (Beaumont)



Mr Roger Towey (Amgen) and Prof John Carey (GUH)



Dr Maurice Barry (Bons Secours, Dublin) and  
Dr Barry O'Shea (St James's)



Prof Gerry Wilson (UCD) and Dr Gary Wright (Musgrave Park, Belfast)



Dr Asif Shah (Navan) and Dr Azhar Abbas (St James's)



Prof Doug Veale (SVUH) and Mr Declan O'Callaghan (Pfizer)

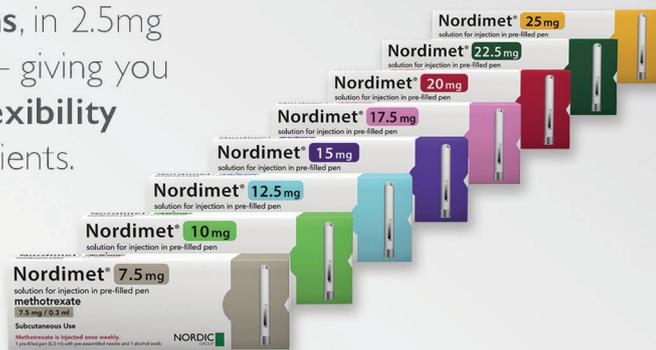
# NORDIMET® PEN

## THE ONLY METHOTREXATE AUTO-INJECTOR FOR PATIENTS WITH RHEUMATOID ARTHRITIS

Featuring a unique **double click mechanism** at the start and end of each injection, a **compact design** and **NO BUTTON TO PRESS** - designed to give confidence to you and your patients



Available in **8 dose presentations**, in 2.5mg increments from 7.5mg to 25mg – giving you a **wide dosage range** and the **flexibility you need** when treating your patients.



## METHOTREXATE AUTO-INJECTOR PEN

### Nordimet (methotrexate) Solution for injection in pre-filled pen

Please refer to the Summary of Product Characteristics for full prescribing information. Further information is available on request.

**Presentation:** Pre-filled pen containing 7.5 mg (in 0.3 ml), 10 mg (in 0.4 ml), 12.5 mg (in 0.5 ml), 15 mg (in 0.6 ml), 17.5 mg (in 0.7 ml), 20 mg (in 0.8 ml), 22.5 mg (in 0.9 ml) and 25 mg (1.0 ml) methotrexate in solution for injection. **Indications:** Active rheumatoid arthritis in adult patients. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate. Severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients. **Dosage and administration:** Nordimet should only be prescribed by physicians with experience in the various properties of the medicinal product and its mode of action. Nordimet is injected once weekly, administered subcutaneously. **Rheumatoid arthritis:** Recommended initial dose is 7.5 mg of methotrexate once weekly. Depending on the individual activity of the disease & patient tolerability, the initial dose may be increased. A weekly dose of 25 mg should in general not be exceeded. Once the desired therapeutic result has been achieved, the dose should be reduced gradually to the lowest possible effective maintenance dose. **Polyarthritic forms of severe, active juvenile idiopathic arthritis:** The recommended dose is 10-15 mg/m<sup>2</sup> BSA per week. In therapy-refractory cases the weekly dose may be increased up to 20mg/m<sup>2</sup> BSA per week. Use in children < 3 years of age is not recommended. **Psoriasis vulgaris and psoriatic arthritis:** A test dose of 5 - 10 mg subcutaneously administered one week prior to initiation of therapy is recommended. Recommended initial dose 7.5 mg methotrexate once weekly. Dose increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate.

Once the desired therapeutic result has been achieved, dose should be reduced gradually to the lowest possible effective maintenance dose. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. Renal impairment, hepatic impairment or elderly patients: Please refer to SmPC. Note: When switching from oral to parenteral use, a reduction in the dose may be required, due to the variable bioavailability of methotrexate after oral administration. **Contraindications:** Hypersensitivity to methotrexate or to any of the excipients. Severe hepatic impairment, if serum bilirubin is > 5 mg/dl (85.5 µmol/l). Alcohol abuse. Severe renal impairment (creatinine clearance < 30 ml/min). Pre-existing blood dyscrasias (e.g. bone marrow hypoplasia, leukopenia, thrombocytopenia or significant anaemia). Immunodeficiency. Serious, acute or chronic infections such as tuberculosis & HIV. Stomatitis. Ulcers of the oral cavity and known active gastrointestinal ulcer disease. Pregnancy. Breast-feeding. Concurrent vaccination with live vaccines. **Special warnings and precautions:** Patients must be clearly advised that the therapy is to be administered once a week, and not every day. Patients receiving therapy should be appropriately monitored. Doses exceeding 20 mg/week can be associated with significant increase in toxicity, especially bone marrow suppression. The possible risks of effects on reproduction, pregnancy loss and congenital malformations should be discussed with male and female patients of childbearing potential. Methotrexate contact with skin and mucosal membranes is to be avoided; in cases of contamination rinse the area with plenty of water. **Interactions:** Consult SPC for detailed information on interactions. **Undesirable effects: See SmPCs for full list of undesirable effects. Very common:** Stomatitis. Dyspepsia. Appetite loss. Abdominal pain. Nausea. Raised liver enzymes. **Common:** Leukopenia. Anaemia. Thrombopenia. Headache. Tiredness. Drowsiness. Pneumonia.

Interstitial alveolitis/pneumonitis. Oral ulcers. Diarrhoea. Exanthema. Erythema. Pruritus. **Uncommon:** Pharyngitis. Pancytopenia. Precipitation of diabetes mellitus. Depression. Enteritis. Pancreatitis. Gastrointestinal ulceration and bleeding. Cirrhosis, Fibrosis and fatty degeneration of liver. Inflammation and ulceration of bladder. Renal impairment. **Rare:** Infection. Conjunctivitis. Sepsis. Allergic reactions. Anaphylactic shock. Hypogammaglobulinaemia. Visual disturbances. Pericarditis. Pericardial effusion. Pericardial tamponade. Thromboembolic events. Pulmonary fibrosis. Pneumocystis carinii pneumonia. Shortness of breath and bronchial asthma. Pleural effusion. Acute hepatitis. Renal failure. Anuria. **Very rare:** Lymphoma. Agranulocytosis. Lymphoproliferative disorders. Severe courses of bone marrow depression. Acute aseptic meningitis. Convulsions. Paralysis. Impaired vision. Retinopathy. Haematemesis. Toxic megacolon. Hepatic failure. Stevens-Johnson syndrome. Toxic epidermal necrolysis. **Not known:** Eosinophilia. Encephalopathy/Leukoencephalopathy. Pulmonary alveolar haemorrhage. Jaw osteonecrosis (secondary to lymphoproliferative disorders). **Legal classification:** POM. **MA numbers:** EU/1/16/1124/001 - 008. **Further information available from:** Nordic Pharma Ltd, 4045 Kingswood Road, Citywest Business Park, Co Dublin. **Date of Prescribing Information:** June 2018. **Item code:** I/18/NOR/007-00.

### Adverse events should be reported.

Reporting forms and information can be found at <http://www.hpra.ie>

Adverse events should also be reported to Nordic Pharma Ireland: [info@nordicpharma.ie](mailto:info@nordicpharma.ie)  
Phone no. +353 (0)1 4004141



## Ioana Tereza Florica ISR Bernard Connor Medal

Tereza Florica is a Canadian third-year graduate entry medical student at University College Cork. She graduated from the Canadian University of McMaster in 2016 with an Honours Bachelor of Science in Neuroscience. She has a special interest in rheumatology and is currently investigating bowel inflammation in patients with Spondyloarthropathies. She hopes to pursue her passions in the field of rheumatology and expand her clinical knowledge.



### CLINICAL DILEMMAS OF CARDIAC INVOLVEMENT IN MYOSITIS

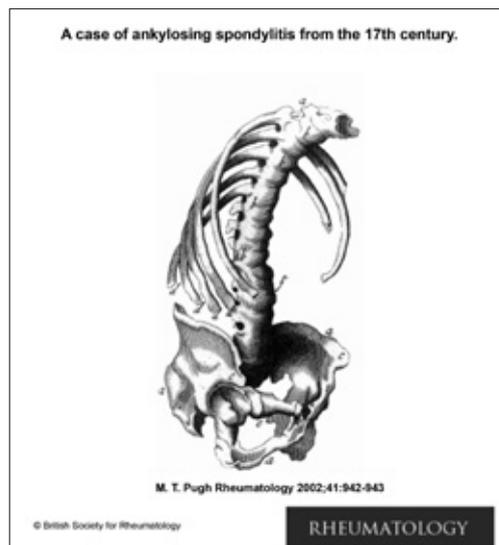
The diversity of myositis disease presentation results in diagnostic difficulty across medical specialties. The extended myositis antibody (EMA) panel, though not yet routine, has documented utility, prognostic value, and structures treatment options<sup>1,2</sup>. However, myocardial involvement is one of the rarer manifestations of myositis (~3%)<sup>3</sup>. Due to the many different symptomatic or asymptomatic presentations, and lack of established diagnostic procedures it can be misdiagnosed. Cardiac MRI shows promise as a tool for detecting both focal and diffuse myocardial involvement and is significantly correlated with elevated troponin I4.

During my rheumatology placement, I came across three patients with diagnostic dilemmas in relation to myocardial involvement of myositis. These difficult cases inspired me to explore this rare and complicated disease.

Patient 1, with a background history of limited scleroderma, (ANA+, ENA-) presented 3 weeks post-partum after a caesarian-section at 34 weeks, complicated by acute HELLP syndrome. Once discharged, she experienced progressive shortness of breath on exertion and fatigability, which she attributed to anemia from pregnancy related blood loss. She then developed PND and orthopnea, with refractory hypertension. This prompted admission under the care of cardiology, where she was treated for protracted pre-eclampsia. Following discharge, she had ongoing symptoms and on review in Rheumatology OPD was found to have elevated creatine kinase (1,853;26-192IU/L), LDH (1180;135-214IU/L), and troponin (545;<14ng/L). She was readmitted, clinically in mild cardiac failure. Cardiac MRI showed no abnormalities to suggest infiltration or scarring of the myocardium. While in hospital, an EMA panel was conducted and revealed positive PM/Scl antibodies, often associated with systemic sclerosis/myositis overlap. The patient improved after treatment with Rituximab and tapering prednisolone.

Patient 2 presented with bilateral lower limb pitting oedema, proximal muscle weakness and a 4-day history of nonpruritic maculopapular rash localized to the upper limbs, abdomen, and thighs. She was also experiencing fatigability and shortness of breath on exertion, but she attributed these symptoms to the onset of menopause. Patient 2 also had remarkably elevated creatine kinase (16,556;26-192IU/L), LDH (7,671;135-214IU/L) and troponin (723;<14ng/L). However, both echocardiogram and cardiac MRI were grossly normal. She is a patient known to the clinic with active rheumatoid arthritis, treated with Adalimumab. An EMA panel revealed positive anti-Jo-1 antibodies; an antibody directed against histidyl-tRNA synthetase and one of the antibodies under the classification of anti-synthetase syndrome. Myocarditis is recognized as a rare but severe manifestation of anti-synthetase syndrome but the criteria for its diagnosis is unclear<sup>3</sup>. In addition, EMG and muscle biopsy findings implied acute myopathy with muscle fiber necrosis. This patient's symptoms were alleviated by treatment with Rituximab.

Patient 3, a previously healthy woman, presented with a 6-week history of fatigue, diaphoresis, rash, insomnia and migrating polyarthralgia. She also experienced occasional palpitations and chest tightness but no dyspnea. She denied all other cardiac and respiratory symptoms. The patient attributed her symptoms to the onset of menopause. She had bilaterally reduced air entry, basal inspiratory crepitations and a soft ejection murmur but no pedal oedema. On admission, troponin levels were elevated and continued to increase over time to a peak of 163(<14ng/L). New ECG changes showed T wave inversions in leads V4, V5, II and III. An echocardiogram was grossly normal while a cardiac MRI showed mediastinal lymphadenopathy and multiple abnormal areas of delayed enhancement suggesting myocardial inflammation. An EMA panel revealed positive PL-12 antibodies, another one of the antibodies under the classification of anti-synthetase syndrome. In this patient, treatment with rituximab was insufficient and thus cyclophosphamide was added, alleviating her symptoms.



# For Her.



**CIMZIA**<sup>®</sup>  
(certolizumab pegol)



**CIMZIA<sup>®</sup> allows for continuity of treatment for your young female (aged 18-45) patients with RA, PsA, axSpA or PsO should they decide to start a family in the future<sup>1,2</sup>**

1. Mariette X, et al. Ann Rheum Dis 2018; 77(2):228-233
2. CIMZIA<sup>®</sup> Summary of Product Characteristics

#### Cimzia<sup>®</sup> Certolizumab Pegol

**Active Ingredient:** Pre-filled syringe and pre-filled pen contain 200 mg certolizumab pegol in one ml. **Indication(s):** *Rheumatoid arthritis (RA):* Cimzia, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Cimzia in combination with methotrexate (MTX), is also indicated in the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX. *Axial spondyloarthritis:* Cimzia is indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising: *Ankylosing spondylitis (AS):* Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). *Axial spondyloarthritis without radiographic evidence of AS:* Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs. *Psoriatic arthritis:* Cimzia in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. *Plaque psoriasis:* Cimzia is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Dosage and Administration:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Cimzia is indicated in adult patients. Patients should be given the reminder alert card. For RA and psoriatic arthritis MTX should be continued during treatment with Cimzia where appropriate. **Loading dose:** The recommended starting dose is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. **Maintenance dose:** RA and Psoriatic Arthritis: The recommended maintenance dose is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dose of 400 mg every 4 weeks can be considered. *Axial spondyloarthritis:* The recommended maintenance dose is 200 mg every 2 weeks or 400 mg every 4 weeks. For the above indications continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment. *Plaque psoriasis:* the recommended maintenance dose is 200 mg every 2 weeks. 400 mg every 2 weeks can be considered in patients with insufficient response. **Missed dose:** Advise patients to inject the next dose as soon as they remember and inject subsequent doses as originally instructed. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients; active tuberculosis or other severe infections such as sepsis or opportunistic infections; moderate to severe heart failure (NYHA classes III/IV). **Warnings & Precautions:** Prior to treatment with Cimzia all patients to be appropriately screened for tuberculosis and results recorded on the patient reminder alert card. In patients with a past history of latent tuberculosis use of anti-tuberculosis therapy must be started before initiation of Cimzia. Treatment must not be initiated until infection is controlled. Some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with Cimzia. Consult SPC for details. Monitor patients closely for signs of infection during and up to 5 months after treatment. Serious infections and opportunistic infections have been reported with some fatal outcomes. Caution is advised in patients with a history of recurring or opportunistic infections including those on concomitant corticosteroid or immunosuppressive medications or elderly. Patients should be tested for HBV infection before initiating treatment with Cimzia and if treated should be continually monitored. HBV reactivation has occurred in chronic carriers with some fatal outcomes. Cimzia should be discontinued and antiviral therapy and supportive treatments initiated. There is an increase in background risk for lymphoma and leukaemia in patients. Periodic skin examination is recommended particularly for patients with risk factors for skin cancers such as melanoma and Merkel's cell cancer. Caution when initiating therapy in patients with a history of malignancies. Data is not available for considering continuing

treatment in patients who have developed lymphoma, leukaemia, mild congestive heart failure and demyelinating disorders. Advise patients to seek immediate medical attention if they develop signs and symptoms suggestive of tuberculosis, blood dyscrasias or infection. Discontinue treatment if patients develop significant haematological abnormalities; lupus-like syndrome; mild congestive heart failure and demyelinating disorder. There is a potential risk of worsening of congestive heart failure with TNF antagonists. COPD and heavy smoking may put patients at greater risk of malignancies. Patients receiving Cimzia may receive vaccination except live vaccines. Cimzia may cause erroneously elevated (aPTT) assay results in patients without coagulation abnormalities. The needle shield contains a natural rubber latex derivative which may cause allergic reactions. **Interactions:** The combination of Cimzia and anakinra or abatacept is not recommended. **Fertility, pregnancy and lactation:** The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last Cimzia dose due to its elimination rate, but the need for treatment of the woman should also be taken into account. Cimzia should only be used during pregnancy if clinically needed. Cimzia can be used during breastfeeding. **Side Effects:** Common adverse-effects ( $\geq 1/100$  to  $<1/10$ ): infections, eosinophilic disorders, leukopenia, headaches, sensory abnormalities, hypertension, nausea, hepatitis (including hepatic enzyme increased), rash, pyrexia, pain, asthenia, pruritus (any site), injection site reactions. **Serious Side effects:** Infections including sepsis, tuberculosis, fungal infections, blood and lymphatic system malignancies, solid organ tumours, non-melanoma skin cancers, pre-cancerous lesions, benign tumours and cysts, gastrointestinal tumours, melanoma, Merkel cell carcinoma, eosinophilic disorders, leukaemia (including neutropenia, lymphopenia), anaemia, lymphadenopathy, thrombocytopenia, thrombocytosis, pancytopenia, vasculitides, lupus erythematosus, drug hypersensitivity (including anaphylactic shock), angioneurotic oedema, sarcoidosis, thyroid disorders, haemosiderosis, suicide attempt, mental impairment, anxiety disorders, sensory abnormalities, peripheral neuropathies, dizziness, tremor, seizure, multiple sclerosis, Guillain-Barré syndrome, visual disorder, tinnitus, vertigo, cardiomyopathies, ischaemic coronary artery disorders, arrhythmias, palpitations, pericarditis, atrioventricular block, hypertension, haemorrhage or bleeding (any site), hypercoagulation, syncope, cerebrovascular accident, arteriosclerosis, Raynaud's phenomenon, asthma, pleural effusion, cough, interstitial lung disease, pneumonitis, ascites, gastrointestinal ulceration and perforation, gastrointestinal tract inflammation, odynophagia, hepatitis (including hepatic enzyme increased), hepatopathy, cholelithiasis, alopecia, new onset or worsening of psoriasis and other skin related conditions, bullous conditions, Stevens-Johnson syndrome, erythema multiforme, lichenoid reactions, renal impairment, nephropathy. **Consult SPC in relation to other side effects.**

**Pharmaceutical Precautions:** Store in refrigerator (2°-8°C). Do not freeze. Keep the pre-filled syringe and pre-filled pen in the outer carton in order to protect from light. **Legal Category:** POM Marketing Authorisation Number(s): EU/1/09/544/001, EU/1/09/544/005 **UK NHS Cost:** £715 per pack of 2 pre-filled syringes or pens of 200 mg each **Marketing Authorisation Holder:** UCB Pharma S.A., Allée de la Recherche 60, 1070 Brussels, Belgium. **Further information is available from:** UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. **Tel:** +44 (0) 1753 777100. **Fax:** +44 (0)1753 536632. **Email:** UCBcares.UK@ucb.com UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland **Tel:** +353 1 4632371 **Fax:** +353 14637396 **Email:** UCBcares.IE@ucb.com **Date of Revision:** 05/2019 (DER-API-IE-CZ-00003). Cimzia is a registered trademark.

#### Adverse events should be reported

Reporting forms and information can be found at: [yellowcard.mhra.gov.uk](http://yellowcard.mhra.gov.uk)  
Adverse events should also be reported to UCB Pharma Ltd



... conti'd

Table 1: Summary of Patient findings

	Peak Troponin	Left Ventricle Ejection Fraction		Cardiac MRI	Treatment
		Echo	cMRI		
Patient 1	545	62.7%	56%	Normal left ventricular function. No delayed myocardial enhancement to suggest infiltration or scarring.	Rituximab
Patient 2	723	65.9%	59%	Normal left ventricular function. No delayed myocardial enhancement to suggest infiltration or scarring.	Rituximab
Patient 3	163	62%	56%	Mediastinal lymphadenopathy and abnormal areas of delayed enhancement suggesting myocardial inflammation.	Rituximab + Cyclophosphamide

Myocarditis as a manifestation of myositis is not well understood. Since patients can present with a variety of symptoms, physicians under different medical specialties are responsible for recognizing the signs of this dangerous but manageable disease. The pathogenesis of disease is still unclear. The three patients described

above have all been diagnosed with myocarditis, but a distinct discrepancy exists between their clinical presentations, imaging, and laboratory findings. Though patient 1 showed the strongest cardiovascular symptoms and elevated troponin, her cardiac imaging was normal. Patient 2 experienced some cardiovascular symptoms and her enzymes were most elevated, but imaging was normal. In contrast, patient 3 showed some cardiovascular symptoms, but her troponin, though abnormal, was significantly less elevated. Patient 3 was the only patient to have abnormal cardiac imaging.

The EMA panel provides some guidance in diagnosing and treating myositis, but associations with myocarditis are not clear. Moreover, the discrepancy between clinical features, laboratory tests, and imaging presents clinical dilemmas in diagnosis and assessing therapeutic response. This series highlights the utility of cardiac MRI in cases with normal echocardiography but emphasizes a clear need for large scale international collaboration in exploring different biomarkers for diagnosing, classifying, and treating myocardial involvement in myositis.

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# ISR Spring Meeting

Provisional Date April 3rd 2020

Athlone

# Adenuric<sup>®</sup>

(febuxostat)

## Treat to target. Daily.<sup>1,2</sup>



**ADENURIC 80 mg and 120 mg film-coated tablets: Abbreviated Prescribing Information** Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

**Presentation:** Film-coated tablets containing 80 mg or 120 mg febuxostat. Also contains lactose monohydrate. **Use:** Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis) in adults.

**Dosage and administration:** Oral use with or without food. Recommended dose is 80 mg once daily. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, 120 mg once daily may be considered. **Older people:** No dose adjustment required. **Renal impairment:** No dosage adjustment necessary in patients with mild or moderate renal impairment. Efficacy and safety not fully evaluated in patients with severe renal impairment. **Hepatic impairment:** Recommended dosage in patients with mild hepatic impairment is 80 mg. Limited information available in patients with moderate hepatic impairment. Efficacy and safety has not been studied in patients with severe hepatic impairment. **Children and adolescents:** Safety and efficacy in children under 18 has not been established. **Organ transplant recipients:** No experience therefore not recommended. **Contraindications:** Hypersensitivity to the active ingredient or to any of the excipients. **Warnings and precautions:** **Cardio-vascular disorders:** **Not recommended in patients with ischaemic heart disease or congestive heart failure.** **Product allergy/hypersensitivity:** Advise patients of signs/symptoms of allergic/hypersensitivity reactions and monitor closely for symptoms. Stop treatment immediately if serious reactions occur, including Stevens-Johnson syndrome, Toxic epidermal necrolysis and acute anaphylactic reaction/shock; do not re-start febuxostat at any time. Severe hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with fever, haematological, renal or hepatic involvement in some cases. **Acute gouty attacks (gout flare):** Do not start treatment until an acute attack of gout has completely subsided. As with other urate lowering medicinal products, gout flares may occur during initiation of treatment. At treatment initiation flare prophylaxis for at least 6 months with an NSAID or colchicine is recommended. If a gout flare occurs during treatment, do not discontinue. Manage the gout flare concurrently as appropriate. Continuous treatment decreases frequency and intensity of gout flares.

**Xanthine deposition:** As with other urate lowering medicinal products, in patients in whom the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. As there has been no experience of treating gout in these patients with febuxostat such use is not recommended. **Mercaptopurine/azathioprine:** Not recommended in patients concomitantly treated with mercaptopurine/azathioprine. Where combination cannot be avoided, monitor patients closely. Dose reduction for mercaptopurine/azathioprine is recommended. **Theophylline:** No pharmacokinetic interaction shown with febuxostat 80 mg, no data for 120 mg. **Liver disorders:** Liver function test is recommended prior to the initiation of therapy and periodically thereafter based on clinical judgement. **Thyroid disorders:** Caution in patients with alteration of thyroid function. **Lactose:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** **Mercaptopurine/azathioprine:** On the basis of the mechanism of action of febuxostat on xanthine oxidase inhibition concomitant use is not recommended. Where the combination cannot be avoided see SmPC for dosing instructions. **Rosiglitazone/CYP2C8 inhibitors:** No dosage adjustment required. **Theophylline:** No special caution advised for 80 mg febuxostat, no data available for 120 mg. **Naproxen and other inhibitors of glucuronidation:** Can be co-administered with naproxen with no dose adjustments necessary. **Inducers of glucuronidation:** Monitoring of serum uric acid is recommended 1-2 weeks after start of treatment with a potent inducer of glucuronidation. Cessation of treatment of an inducer might lead to increased plasma levels of febuxostat. **Colchicine/indometacin/hydrochlorothiazide/warfarin:** Can

be co-administered with colchicine or indometacin with no dose adjustments necessary. No dose adjustment necessary when administered with hydrochlorothiazide. No dose adjustment necessary for warfarin when administered with febuxostat. **Desipramine/CYP2D6 substrates:** Co-administration with other CYP2D6 substrates is not expected to require any dose adjustment for those compounds. **Antacids:** May be taken without regard to antacid use. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. Effect on fertility unknown. **Side-Effects:** **Clinical Studies and post-marketing experience:** Common (1-10%): Gout flares, headache, diarrhoea\*, nausea, liver function test abnormalities\*, rash, oedema. Uncommon (0.1-1%): Blood thyroid stimulating hormone increased, diabetes mellitus, hyperlipidemia, decrease appetite, weight increase, decreased libido, insomnia, dizziness, paraesthesia, hemiparesis, somnolence, altered taste, hypoaesthesia, hyposmia, atrial fibrillation, palpitations, ECG abnormal, hypertension, flushing, hot flush, dyspnoea, bronchitis, upper respiratory tract infection, cough, abdominal pain, abdominal distension, gastro-oesophageal reflux disease, vomiting, dry mouth, dyspepsia, constipation, frequent stools, flatulence, gastrointestinal discomfort, cholelithiasis, dermatitis, urticaria, pruritus, skin discoloration, skin lesion, petechiae, rash macular, rash maculopapular, rash papular, arthralgia, arthritis, myalgia, musculoskeletal pain, muscle weakness, muscle spasm, muscle tightness, bursitis, renal failure, nephrolithiasis, haematuria, pollakiuria, proteinuria, erectile dysfunction, fatigue, chest pain, chest discomfort, blood amylase increase, platelet count decrease, WBC decrease, lymphocyte count decrease, blood creatinine increase, blood creatinine increase, haemoglobin decrease, blood urea increase, blood triglycerides increase, blood cholesterol increase, haematocrit decrease, blood lactate dehydrogenase increased, blood potassium increase. Rare (0.1-0.01%): Pancytopenia, thrombocytopenia, agranulocytosis\*\*, anaphylactic reaction\*\*, drug hypersensitivity\*\*, blurred vision, weight decrease, increase appetite, anorexia, nervousness, tinnitus, pancreatitis, mouth ulceration, hepatitis, jaundice\*\*, liver injury\*\*, Toxic epidermal necrolysis\*\*, Stevens-Johnson Syndrome\*\*, DRESS\*\*, angioedema\*\*, generalized rash (serious)\*\*, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic\*\*, rash erythematous, rash morbilliform, alopecia, hyperhidrosis, rhabdomyolysis\*\*, joint stiffness, musculoskeletal stiffness, tubulointerstitial nephritis\*\*, micturition urgency, thirst, blood glucose increase, activated partial thromboplastin time prolonged, red blood cell count decrease, blood alkaline phosphatase increase, blood creatine phosphokinase increase\*\*. \*Treatment-emergent non-infective diarrhoea and abnormal liver function tests in combined Phase III studies more frequent in patients concomitantly treated with colchicine. \*\*Adverse reactions coming from post-marketing experience. Rare serious hypersensitivity reactions including Stevens-Johnson Syndrome and anaphylactic reaction/shock have occurred in post-marketing experience. Hypersensitivity reactions to febuxostat can be associated with the following symptoms: skin reactions characterised by infiltrated maculopapular eruption, generalised or exfoliative rashes, also skin lesions, facial oedema, fever, haematologic abnormalities such as thrombocytopenia, and single or multiple organ involvement (liver and kidney including tubulointerstitial nephritis). Gout flares commonly observed soon after treatment start and in first months. Frequency decreases after time. Gout flare prophylaxis is recommended. Please consult the SmPC for further information. **Pack sizes:** 80 mg and 120 mg tablets: 28 film-coated tablets. **Legal category:** POM **Marketing authorization number:** EU/1/08/447/001, 003, 014, 020. **Marketing authorization holder:** Menarini International Operations Luxembourg S.A., Avenue de la Gare, L-1611 Luxembourg, Luxembourg **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924 or may be found in the SmPC. **Last updated:** January 2019.

**References:** 1. Adenuric 80 mg SmPC. October 2018. 2. Adenuric 120 mg SmPC. May 2018.

ADENURIC<sup>®</sup> is a trademark of Teijin Limited, Tokyo, Japan

Date of item: February 2019  
IR-ADEN-01-2019



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- ✓ Lasting improvement in enthesitis and dactylitis
- ✓ Effective in axial involvement
- ✓ Lasting relief of skin symptoms
- ✓ Visible improvements in nail symptoms

...with just 4 maintenance doses per year<sup>7\*\*</sup>

\*GRAPPA recommends Stelara® as a 1<sup>st</sup> line biologic in psoriatic arthritis patients with enthesitis, dactylitis, skin & nail symptoms and axial disease (conditionally)  
\*\*Following a loading dose at week 0 and week 4



**STELARA®** 45 mg and 90 mg solution for injection and 130 mg concentrate for solution for infusion  
**PRESCRIBING INFORMATION**  
**ACTIVE INGREDIENTS:** Ustekinumab  
Please refer to Summary of Product Characteristics (SmPC) before prescribing.  
**INDICATIONS:** **Plaque psoriasis adults:** Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporin, methotrexate or PUVA.  
**Plaque psoriasis paediatrics:** Moderate to severe plaque psoriasis in adolescent patients from 12 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.  
**Psoriatic arthritis:** Alone or in combination with methotrexate for treatment of active psoriatic arthritis in adult patients when response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.  
**Crohn's Disease:** Treatment of adult patients with moderately to severely active Crohn's disease who had inadequate response with/lost response to/were intolerant to either conventional therapy or TNF $\alpha$  antagonist or have contraindications to such therapies.  
**DOSAGE & ADMINISTRATION:** Adults: Under guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis/psoriatic arthritis/Crohn's disease.  
**Psoriasis or psoriatic arthritis:** Subcutaneous (s.c.) injection. Avoid areas with psoriasis. Self-injecting patients or caregivers ensure appropriate training. Physicians are required to follow-up and monitor patients.  
**Plaque psoriasis, adults & elderly:** Patients  $\leq 100$ kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients  $>100$  kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients).  
**Plaque psoriasis paediatrics (12 years and older):** Patients  $<60$  kg, 0.75 mg/kg at week 0, followed by 0.75 mg/kg at week 4 then every 12 weeks thereafter. Patients  $\geq 60$  kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients

$>100$  kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks.  
**Psoriatic arthritis, adults & elderly:** 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight  $>100$  kg.  
Consider discontinuation if no response after 28 weeks.  
**Crohn's Disease:** Initial single intravenous infusion dose based on body weight (250 mg or 390 mg or 520 mg) diluted in sodium chloride solution and given over at least one hour. At week 8 after intravenous dose, 90 mg s.c. dose is given, followed by every 12 weeks (or 8 weeks based on clinical judgement). Consider discontinuation if no response at 16 weeks. Immunomodulators and/or corticosteroids may be continued but consider reducing/discontinuing corticosteroids if responding to Stelara. If therapy interrupted, resume s.c. every 8 weeks if safe/effective.  
**Children: <12 years - Not recommended for psoriasis. <18 years - Not recommended for psoriatic arthritis and Crohn's disease. Renal & Hepatic impairment: Not studied.**  
**CONTRAINDICATIONS:** Immunodeficiency to product; clinically important, active infection.  
**SPECIAL WARNINGS & PRECAUTIONS: Infections:** Potential to increase risk of infections and reactivate latent infections. Caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis prior to initiation of STELARA. Consider anti-tuberculosis therapy prior to initiation of STELARA in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, closely monitor and STELARA should not be administered until infection resolves.  
**Malignancies:** Potential to increase risk of malignancy. No studies in patients with history of malignancy or in patients who develop malignancy while receiving STELARA. Monitor all patients, in particular those older than 60, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment for non-melanoma skin cancer. **Concomitant immunosuppressive therapy:** Caution, including when changing immunosuppressive/biologic agents.  
**Hypersensitivity reactions:** Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur appropriate therapy should be instituted

and STELARA discontinued. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. **Immunotherapy:** Not known whether STELARA affects allergy immunotherapy.  
**Serious skin conditions:** Exfoliative dermatitis reported following treatment. Discontinue STELARA if drug reaction is suspected.  
**SIDE EFFECTS: Common:** upper respiratory tract infection, nasopharyngitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. **Other side effects:** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis, lower respiratory tract infection. Studies show adverse events reported in  $\geq 12$  year olds with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis.  
**Refer to SmPC for other side effects.**  
**FERTILITY:** The effect of ustekinumab has not been evaluated.  
**PREGNANCY:** Should be avoided. Women of childbearing potential: Use effective contraception during treatment and for at least 15 weeks post-treatment.  
**LACTATION:** Limited data in humans.  
**INTERACTIONS:** In vitro, STELARA had no effect on CYP450 activities. **Vaccinations:** Live vaccines should not be given concurrently with STELARA, and should be withheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on secondary transmission of infection by live vaccines in patients receiving STELARA. **Concomitant immunosuppressive therapy:** Psoriasis: Safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. Psoriatic arthritis: concomitant MIX did not appear to affect STELARA. Crohn's disease: concomitant immunosuppressive or corticosteroid therapy did not appear to affect STELARA.  
**Refer to SmPC for full details of interactions.**  
**LEGAL CATEGORY:** Prescription Only Medicine.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBERS:		
PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBERS
45 mg	3 vials	EU/1/09/454/001
45 mg	1 x 0.5 ml pre-filled syringe	EU/1/09/454/003
90 mg	1 x 1.0 ml pre-filled syringe	EU/1/09/454/004
130 mg	1 vial	EU/1/09/454/005

**MARKETING AUTHORISATION HOLDER:** JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.  
**FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.  
Prescribing information last revised: 09/2017

**Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via:** HPRM Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.stelara.ie](http://www.stelara.ie), E-mail: [medinfo@stelara.ie](mailto:medinfo@stelara.ie). Adverse events should also be reported to Janssen-Cilag Limited on +411494 967447 or at [dsafety@jci.jnj.com](mailto:dsafety@jci.jnj.com).

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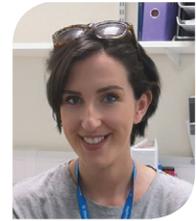
**REFERENCES:** 1.Coates LC et al. Arthritis Rheumatol 2016;68:1060-1071 2. Kavanaugh A et al. Arthritis Care Res (Hoboken) 2015;doi: 10.1002/acr.22645. 3. Kimball AB et al. J Eur Acad Dermatol Venerol. 2013;27:1535-1545. 4. Rich P et al. Br J Dermatol. 2014; 170:398-407. 5. Molmnes I et al. Lancet. 2013;382:9894-780-789. 6. Ritchin C et al. Ann Rheum Dis. 2014;73:990-999. 7. Stelara® Summary of Product Characteristics, available at [www.medicines.ie](http://www.medicines.ie) PHIR/STE/0718/0005 | Date of Preparation: July 2018



## Young Investigator Award 2019

### Dr Mary Canavan

Mary obtained her PhD in the area of Immunology in 2012. She undertook her first postdoctoral position with Prof. Doug Veale in St Vincent's University Hospital, where she examined the role of hypoxia and metabolic dysfunction in rheumatoid arthritis. Subsequently, she was awarded an Irish Research Council Postdoctoral Enterprise Fellowship with Prof. Ursula Fearon in Trinity College Dublin in collaboration with Janssen Pharmaceuticals. Her research interests include examining the immune infiltration in particular dendritic cells and T cells in inflammatory arthritis and examining the effects of the joint microenvironment on immune cell activation. She is an active member of the European Rheumatology Network – EMEUNET where she has previously sat on the leadership committee. Finally she is associate editor within the translational research section of BMC Rheumatology.



## THE SYNOVIAL MICROENVIRONMENT IN RHEUMATOID ARTHRITIS INDUCES METABOLIC AND FUNCTIONAL ADAPTATIONS IN DENDRITIC CELLS.

### Author(s)

Mary Canavan 1, Trudy McGarry 1, Viviana Marzalioli 1, Douglas J Veale 2, Ursula Fearon 1

### Department(s)/Institutions

1 Molecular Rheumatology, Trinity Biomedical Sciences Institute, Trinity College Dublin 2 Centre for Arthritis and Rheumatic Diseases, St Vincents University Hospital, Dublin

### Introduction

Immune cells infiltrating the synovium have increased bioenergetic demands which leads to a shift in their metabolic profile. This involves the activation of metabolic pathways which is essential for immune cell function. Proinflammatory DC have previously been identified within the RA synovium however the contribution of the synovial microenvironment to their function and metabolic adaptations is unknown.

### Aims/Background

To examine if the unique synovial RA microenvironment contributes to DC function, phenotype and metabolism.

### Method

Immature DC were derived from CD14<sup>+</sup> monocytes in the presence of GM-CSF (50ng/ml) and IL-4 (70ng/ml). Synovial tissue explants were cultured for 24hr allowing the spontaneous release of cytokines and soluble mediators into the culture medium. MoDC were cultured in the presence of explant conditioned medium (ECM) for 24hrs after which phagocytosis, costimulation and expression of inflammatory mediators was assessed by flow cytometry and RT-PCR respectively. To investigate the energy pathways used by DC exposed to synovial ECM, MoDC were treated for 6hr and glucose uptake (2NBDG) was assessed by flow cytometry, glycolytic genes were assessed by RT-PCR and the XFeExtracellular Flux Analyzer will be used to measure both mitochondrial respiration and glycolysis.

### Results

MoDC stimulated with ECM are significantly less phagocytic ( $p < 0.05$ ), have increased expression of CD83 ( $p < 0.05$ ), and express higher levels of IL-12p40, IL-12p19, IL-1 $\beta$ , ICAM-1 and CCR7 (all  $p < 0.05$ ). Moreover the expression of CCR5 is significantly decreased ( $p < 0.01$ ) collectively indicating that the synovial microenvironment induces DC maturation. In the presence of ECM, glucose uptake is significantly increased ( $p < 0.05$ ) while the expression of glycolytic genes such as Hexokinase 2, PDK1, PDK2, PFKFB3, and H6PD were also upregulated. Moreover, using the XFeExtracellular Flux Analyzer, there is a significant increase in ECAR at 1hr, 3hr and 6hr post ECM exposure ( $p < 0.05$ ) in addition to a significant increase in the maximal glycolytic capacity ( $p < 0.01$ ).

### Conclusions

These data suggests that the synovial microenvironment can induce inflammatory and glycolytic changes in MoDC. Future work will aim to reduce the inflammatory potential of synovial DC through metabolic manipulation.

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[tom.odwyer@genomicsmed.ie](mailto:tom.odwyer@genomicsmed.ie)



[www.genomicsmed.ie](http://www.genomicsmed.ie)



**Oral Presentations**  
**Thursday, 26 September 2019**

**Clinical Presentations**

Abstract No.	Name	Title of Paper	Time
19A142	Siobhan Clifford	The added utility of the EMA panel to the clinical and pharmacological management of suspected inflammatory conditions	10.15
19A155	Catherine Hughes	Respiratory Involvement in Relapsing Polychondritis- a single centre study	10.25
19A163	Niamh Morgan	The Genetic and Molecular Dissection of an Early-Onset Familial Mucocutaneous Ulcerative Condition	10.35
19A181	Ovgu Kul Cinar	Can high ANA titre combined with clinical features predict developing autoimmune conditions in children?	10.45

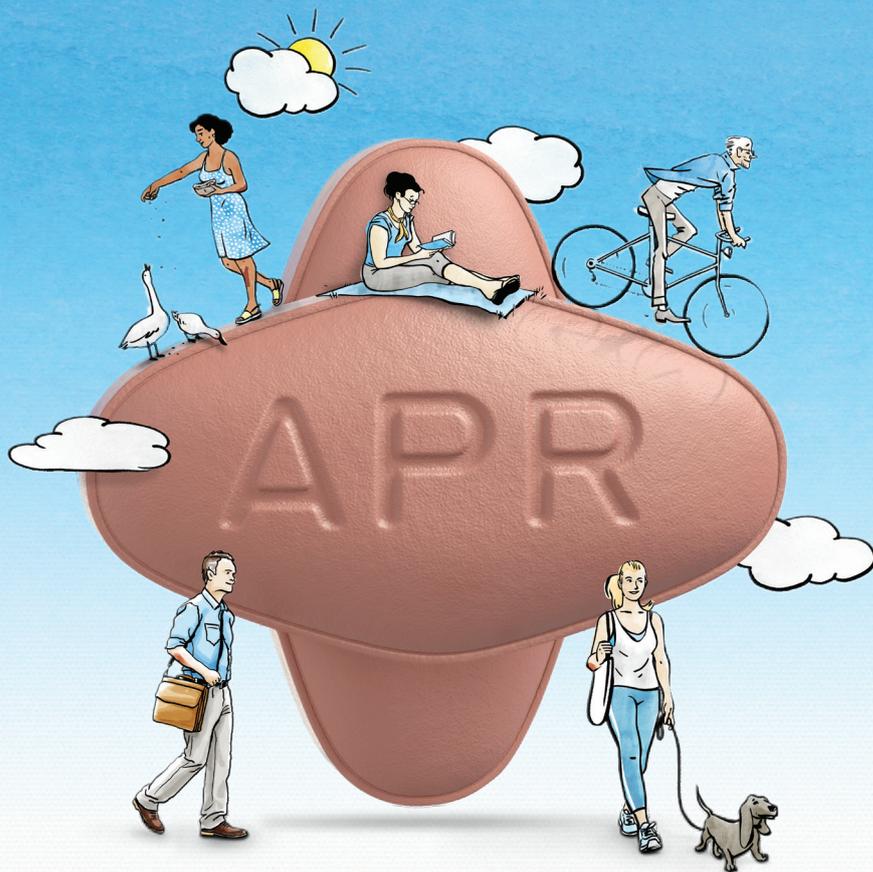
**Scientific Presentations**

Abstract No.	Name	Title of Paper	Time
19A110	Achilleas Floudas	Increased T Cell Plasticity with Dysregulation of Tfh, Tph and Treg Cell Responses in Children with JIA and Down Syndrome-associated Arthritis.	15.10
19A137	Clare Cunningham	The role of cellular metabolism in Rheumatoid and Psoriatic Arthritis	15.20
19A138	Megan Hanlon	Distinct monocyte and macrophage inflammatory and bioenergetic profiles in Rheumatoid Arthritis	15.30
19A154	Rochelle Dowding	Inhibition of glycolytic pathways induce resolution of Inflammation	15.40

**Friday 27 September 2019**

**Oral Presentations - Case Reports**

Ref. No.	Identity of Cases not to be disclosed prior to meeting. Audience Participation units available	Time
119	Case 1	9.30
134	Case 2	9.45
146	Case3	10.00
173	Case 4	10.15




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 (apremilast) 30mg tablets

# RESULTS

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OTEZLA, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy.<sup>1</sup>

*How can OTEZLA help your patients with moderate psoriatic arthritis?*

**Prescribing Information:** OTEZLA<sup>®</sup> (apremilast) 10mg, 20mg and 30mg film coated-tablets. Refer to the Summary of Product Characteristics (SPC) before prescribing. Further information is available upon request.

**Presentation:** 10mg, 20mg and 30mg film coated-tablets.

**Indications:** Psoriatic arthritis: OTEZLA<sup>®</sup>, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. Psoriasis: OTEZLA<sup>®</sup> is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA).

**Dosage and administration:** Treatment with OTEZLA<sup>®</sup> should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of OTEZLA<sup>®</sup> is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required per the following schedule: Day 1: 10mg in the AM; Day 2: 10mg in the AM and 10 mg in the PM; Day 3: 10mg in the AM and 20mg in the PM; Day 4: 20mg in the AM and 20mg in the PM; Day 5: 20mg in the AM and 30mg in the evening; Day 6 and thereafter: 30mg twice daily. No re-titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient's response to treatment should be evaluated on a regular basis.

**Special populations:** Elderly patients: No dose adjustment is required for this patient population. Patients with renal impairment: No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of OTEZLA<sup>®</sup> should be reduced to 30mg once daily in patients with severe renal impairment (creatinine clearance of less than 30mL per minute estimated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that OTEZLA<sup>®</sup> is titrated using only the AM doses and the evening doses be skipped. Patients with hepatic impairment: No dose adjustment is necessary for patients with hepatic impairment. Paediatric population: The safety and efficacy of OTEZLA<sup>®</sup> in children aged 0 to 17 years have not been established. No data is available.

**Contraindications:** Hypersensitivity to the active substance(s) or to any of the excipients. OTEZLA<sup>®</sup> is contraindicated in pregnancy. Pregnancy should be excluded before treatment can be initiated.

**Special warnings and precautions:** Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Severe diarrhoea, nausea, and vomiting associated with the use of Otezla has been reported. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older may be at a higher risk of complications. Discontinuation of treatment may be necessary. OTEZLA<sup>®</sup> is associated with an increased risk of psychiatric disorders such as insomnia and depression. Instances of suicidal ideation and behaviour, including suicide, have been observed in patients with or without history of depression. The risks and benefits of starting or continuing treatment with OTEZLA<sup>®</sup> should be carefully assessed if patients report previous or existing psychiatric symptoms or if concomitant treatment with other medicinal products likely to cause psychiatric events is intended. Patients and caregivers should be instructed to notify the prescriber of any changes in behavior or mood and of any suicidal ideation. If patients suffered from new or worsening psychiatric symptoms, or suicidal ideation or suicidal attempt is identified, it is recommended to discontinue treatment with OTEZLA<sup>®</sup>. OTEZLA<sup>®</sup> should be dose reduced to 30mg once daily in patients with severe renal impairment. OTEZLA<sup>®</sup> may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. OTEZLA<sup>®</sup> should not be used during breastfeeding. No fertility data is available in humans.

**Interactions:** Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducer, rifampicin, resulted in a reduction of systemic exposure of OTEZLA<sup>®</sup>, which may result in a loss of efficacy of OTEZLA<sup>®</sup>. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with OTEZLA<sup>®</sup>

is not recommended. In clinical studies, OTEZLA<sup>®</sup> has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and OTEZLA<sup>®</sup>. OTEZLA<sup>®</sup> can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between OTEZLA<sup>®</sup> and methotrexate in psoriatic arthritis patients. OTEZLA<sup>®</sup> can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between OTEZLA<sup>®</sup> and oral contraceptives containing ethinyl estradiol and norgestimate. OTEZLA<sup>®</sup> can be co-administered with oral contraceptives.

**Side effects:** The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tension headache. The most common adverse reactions leading to discontinuation during the first 16 weeks of treatment were diarrhoea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Very commonly reported adverse events are listed as: diarrhoea\* and nausea\*. Common adverse events are listed as: bronchitis, upper respiratory tract infection, nasopharyngitis\*, decreased appetite\*, insomnia, depression, migraine\*, tension headache\*, headache\*, cough, vomiting\*, dyspepsia, frequent bowel movements, upper abdominal pain\*, gastroesophageal reflux disease, back pain\*, fatigue. Prescribers should consult the summary of product characteristics in relation to other side-effects. Hypersensitivity\* and risk of triggering suicide\* have also been reported. \*At least one of these was reported as serious or could be considered serious.

**Legal category:** POM **Marketing authorisation numbers:** EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. **Marketing authorisation holder:** Celgene Europe BV, Winthontlaan 6 N, 3526KV Utrecht, Netherlands. **For further information contact:** Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom Tel: +44(0)208 831 8300

**Date of preparation:** July 2018 **Approval code:** UK-OTZ180094

Please report any suspected adverse reactions directly to the Health Products Regulatory Authority (HPRA) using the online forms at [www.hpra.ie](http://www.hpra.ie) or the freepost reporting system

Adverse events should also be reported to Celgene Drug Safety  
Tel: 1800 936 217 Fax: 1800 936 477

#### References:

1. OTEZLA (apremilast) 30 mg tablets. Summary of Product Characteristics. Celgene Europe B.V.
2. Lebwohl MG, et al. *J Am Acad Dermatol.* 2014;70(5):871-881.
3. McInnes I, et al. *Ann Rheum Dis.* 2018;77:1588-1589.AB0927.
4. Mease P, et al. *Ann Rheum Dis.* 2018;77:201-202.OP0309.

Date of preparation: March 2019  
PM-IE-OTZ-0031

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(19A142) ABSTRACT 1

ORAL PRESENTATION (CLINICAL)

The added utility of the EMA panel to the clinical and pharmacological management of suspected inflammatory conditions

Author(s)

Siobhan Clifford, Dr. Liam Chawke, Dr. Gráinne Murphy, Dr. John Ryan

Department(s)/Institutions

Department of Rheumatology, CUH

Introduction

The idiopathic inflammatory myopathies are a rare collection of disorders primarily characterised by proximal muscle weakness sometimes accompanied by cutaneous manifestations, Raynaud's syndrome, interstitial lung disease and arthropathy. The introduction of the EMA panel, testing for myositis specific and myositis associated antibodies (MSA/MAA) provides an additional mode of investigation which helps further refine inflammatory diagnoses and management.

Aims/Background

The objectives of the study are:

- 1. To determine the prevalence of autoantibodies from the EMA panel results
2. To identify disease manifestation of patients who have a positive EMA panel
3. To establish if the presence of certain autoantibodies alters a diagnosis or treatment

Method

This is a retrospective chart review of all Cork University Hospital patients who had a positive EMA panel test between January 2013 and June 2018. Data was obtained from CUH immunology lab archives along with individual patient charts and was compiled in a password protected Excel spreadsheet. SPSS version 24 was used to analyse the data.

Results

25.5% of 337 EMA panel tests during the specified time -frame were positive for one or more MSA/MAAs. Of those, 82 charts were available and analysed. The most prevalent antibodies were Ro-52 (33%), PMSCl-75 (18%), Mi-2a/b (15%) and TIF1-gamma (10%). The most common disease presentation was ILD at 57% followed by arthropathy with a prevalence of 30%. Raynaud's and myositis were also common findings with a prevalence of 29% each individually. 28% experienced cutaneous manifestations. Following the EMA panel, 40% patients had their diagnosis changed or refined according to antibodies present. Of those who followed-up, 62% experienced an improvement in symptoms subsequent to medication alterations following EMA panel.

Conclusions

Use of the EMA panel may lead to a change in diagnosis for 40% patients thus leading to adjustment of treatment and improvement of disease manifestations. Despite only 29% presenting with clinical myositis, 39% patients went on to have a myositis-related diagnosis following EMA test further proving its use clinically. However, due to low prevalence of the IIMs, a longer-term study is required to precisely elucidate correlation between antibodies, diagnoses and treatment success.

Table with 6 columns: Antibody, ILD, Raynaud's, Cutaneous lesions, Myositis, Arthropathy. Rows include Ro-52 (31%), PMSCl-75 (18%), PMSCl-100 (7%), Ku (8%), MDA-5 (3.5%), TIF1 gamma (8%), Mi-2 beta (14%), PL-7 (6%), PL-12 (3.6%), NXP-2 (1.2%), SAE-1 (1.2%), SRP (1.2%), Multiple weak, equivocal myositis Abs (1.2%).

(19A155) ABSTRACT 2

ORAL PRESENTATION (CLINICAL)

Respiratory Involvement in Relapsing Polychondritis- a single centre study

Author(s)

Catherine D Hughes, Begona Lopez Garcia, Ken Chee Cheah, Yih Jia Poh, Shirish R Sangle, David D'Cruz

Department(s)/Institutions

The Louise Coote Lupus Unit, Guy's and St Thomas' Hospital, London UK

Introduction

Relapsing polychondritis (RP) is a rare immune mediated inflammatory condition that may result in destruction of cartilaginous tissues. Diagnostic delay is common due to its rarity and heterogeneous clinical spectrum.

Aims/Background

Pulmonary manifestations are common and are associated with significant morbidity and mortality.

Method

Retrospective data analysis of patients attending the Louise Coote Lupus Unit with a clinical diagnosis of RP, focused on those with respiratory involvement. We used McAdams classification criteria. All patients had lung function tests, high resolution CT imaging and bronchoscopy / laryngoscopy wherever necessary plus inflammatory markers and serology to exclude illnesses such as ANCA positive vasculitis.

Results

We identified 57 patients with a diagnosis of RP, respiratory involvement in 23 patients(40%). 18(78%) patients were Caucasian, 3(13%) Afro-Caribbean and 2(9%) Asian. 16(70%) patients presented with respiratory symptoms ranging from mild asthma-like illness to requiring emergency tracheostomy. Median age at symptom onset varied from 18-70 (median age of 41). Mean diagnostic delay of 82 months. 32/57 patients fulfilled McAdams classification criteria. The other 25 patients had clinical presentations compatible with RP. Median ESR was 10(5-70) mm/hour and CRP was 6(1- 110) mg/l. Respiratory complications: 6 patients had tracheomalacia, 5 had tracheal stenosis +/- thickening, 8 had tracheal and bronchial collapse +/- stents, 2 had an emergency tracheostomy. Most patients were on a combination of oral prednisolone (PRED) and disease modifying anti-rheumatic drugs (DMARDs). 4 patients received biologics (1= Rituximab, 2=Infliximab, 1=Adalimumab). 2 patients did not respond to treatment (Rituximab and Infliximab). 2 patients had a good response. 5 patients required CPAP to maintain airways patency due to respiratory collapse. Number of other organ involvement: 7/23 eyes 12/23 ears, 7/23 nose, 17/23 airways, 14/23 chest wall/joints. One patient had 5 organ involvement, three had 4 organ involvement, six had 3 organ involvement, nine patients had 2 organ involvement and four patients had only respiratory involvement.

Conclusions

All RP patients should be evaluated for pulmonary involvement and early detection may help to prevent damage. Immunosuppressive agents should be considered as soon as the diagnosis of RP with respiratory involvement is established. The role of biologic therapy in treatment resistant patients is uncertain.

Table with 12 columns: No., Gender, Ethnicity, Airway involvement, Stenosis/malacia, Tracheal collapse, ESR, CRP, Proteinuria, ANCA/AMA/ASO, Emphysema, Pleural effusion, Death. Rows 1-18.



(19A163) ABSTRACT 3

ORAL PRESENTATION  
(CLINICAL)

**The Genetic and Molecular Dissection of an Early-Onset Familial Mucocutaneous Ulcerative Condition**

**Author(s)**

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**Introduction**

Behcet's disease (BD) is a heterogeneous multifactorial auto-inflammatory condition characterised by recurrent episodes of oral and genital ulceration, uveitis and skin lesions, with less frequent involvement of the gastrointestinal tract, large blood vessels and central nervous system. Recent studies reported monogenic mucocutaneous ulcerative syndromes with similarities to BD in a number of un-related families caused by mutations in NF- $\kappa$ B pathway genes; RELA, a transcription factor of the NF- $\kappa$ B family, and TNFAIP3, a negative regulator of NF- $\kappa$ B activity and inflammatory cytokine production. The NF- $\kappa$ B pathway is a 'master-regulator' of immune and inflammatory signalling with the ability to control expression of genes associated with inflammation, apoptosis and proliferation.

**Aims/Background**

Five multi-case Irish families have been identified with a BD-like illness, primarily involving childhood-onset chronic oral and genital ulcers, whereby the genetic and molecular basis is unknown.

**Method**

Whole exome sequencing (WES) was applied to identify potential disease-causing mutations. Cell-based approaches using a range of experimental models will subsequently be used to elucidate the biological impact of the mutations.

**Results**

In the largest family, WES revealed segregation of a mutation in RELA (p65) with the condition. The mutation involves a cytosine deletion causing a His487ThrfsTer7 frameshift, resulting in a truncated protein. Using PBMCs isolated from patient and non-affected donor blood, it was found that the mutant is expressed at similar levels to wild-type p65. Overexpression studies in RelA<sup>-/-</sup> mouse embryo fibroblast (MEF) cells have revealed that the expression of the mutant significantly decreases NF- $\kappa$ B activity compared to the wild-type. Preliminary findings in RelA<sup>-/-</sup> MEF cells suggest that the expression of the mutant protein affects cellular apoptotic signalling processes. Genotyping of this variant in the other families revealed the presence of the wild-type allele only, suggesting genetic heterogeneity. Current genetic analysis of the remaining families with this condition is expected to reveal novel mutations.

**Conclusions**

This work has identified a novel mutation associated with a rare familial mucocutaneous ulcerative condition. Our study will further inform on the genetic basis and biological mechanism of a BD-like illness. This may lead to better, personalised treatment for patients resulting in earlier disease control and reduced tissue damage.

(19A181) ABSTRACT 4

ORAL PRESENTATION  
(CLINICAL)

**Can high ANA titre combined with clinical features predict developing autoimmune conditions in children?**

**Author(s)**

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**Introduction**

Antinuclear antibodies (ANA) are autoantibodies that recognise cellular antigens found predominantly in the cell nucleus. They are associated with numerous autoimmune diseases such as systemic lupus erythematosus, but may also be found in infectious diseases, malignancies and healthy individuals.

**Aims/Background**

ANA is routinely requested as part of an initial work-up for autoimmune conditions. In healthy children (5-18%), ANA titres of 1/80 to 1/320 have been reported. Over time proportion will decrease in titre or disappear. A prospective study of healthy children with positive ANA found that children who developed autoimmune disease had clinical features at presentation. Therefore, the usefulness of a positive ANA result for diagnosing autoimmune conditions is limited without clinical correlation.

The aim of our study was to assess whether high ANA titre and clinical features at first presentation could predict final diagnosis.

**Method**

A single centre (GOSH), retrospective study. The immunology laboratory provided a list of positive ANA results. A retrospective chart review was performed to ascertain presence or absence of clinical features at presentation under the five following titles: Arthritis, skin involvement, eyes, CNS involvement and raynaud's. We then reviewed the last clinical contact to document confirmed diagnosis.

**Results**

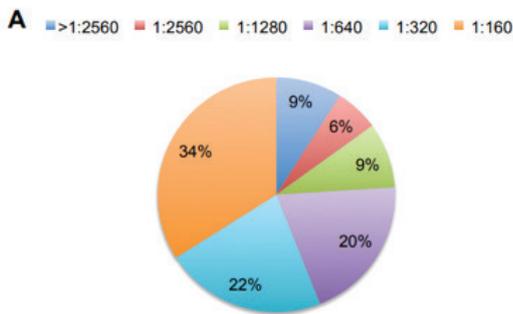
We performed a retrospective chart review on 1354 children (67% female; median age 7.5 years (0.1-17.5); median follow-up 4.8 years (0-18)) with positive ANA results (titres 1/160, 1/320, 1/640, 1/1280, 1/2560 and >1/2560). Figure 1A summarises the ANA titres observed in our cohort. Figure 2A reports ANA titres at first presentation in relation to final diagnosis. A titre of 1/640 or above was most commonly seen (>50%) in children with an autoimmune rheumatology condition. In fact, children with the highest titre (>1:2560) were significantly more likely to be diagnosed with one of these conditions. Finally, we looked at the number of presenting features and correlated with final diagnosis. Those diagnosed with CTD were most likely to present with more clinical features (p<0.0001).

**Conclusions**

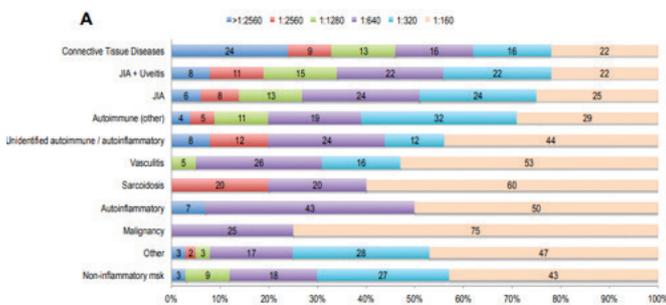
This study suggests that, patients presenting with higher ANA titres and a combination of clinical features at presentation should be assessed systematically and followed-up as they may have increased risk of an autoimmune rheumatological diagnosis.



Figure



Figure



(19A110) ABSTRACT 5

ORAL PRESENTATION (SCIENTIFIC)

Increased T Cell Plasticity with Dysregulation of Tfh, Tph and Treg Cell Responses in Children with JIA and Down Syndrome-associated Arthritis.

Author(s)

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Introduction

Juvenile idiopathic arthritis (JIA) is the most common inflammatory arthritis in children, however an aggressive, erosive and previously underdiagnosed arthritis of little known immunological mechanism, occurs 20-times more frequently in children with Down syndrome (Trisomy 21-T21). We have recently described for the first time the clinical features of DA, this study characterises T-and B-cell polyreactivity, T follicular helper (Tfh), pathologically expanded T helper (Tph) and regulatory (Treg) T cell responses and synovial inflammation in Down syndrome-associated Arthritis (DA).

Aims/Background

Characterization of B cell subpopulation distribution in children with DA, JIA, T21 and healthy controls.

Identification and enumeration of plastic and polyreactive Tfh, Tph and Th cell responses in children with DA.

Evaluation of potential Regulatory cell deficit and synovial inflammation in children with DA.

Method

Multiparametric flow-cytometric analysis, SPICE algorithm and tsNE were utilised to examine peripheral blood B-cell populations and T-cell cytokine responses following in vitro stimulation in children with DA, JIA, T21 and healthy controls (HC). Tfh and Tph cell frequency and origin, in addition to Treg cell frequency were also evaluated. Synovial inflammation was assessed by immunohistology.

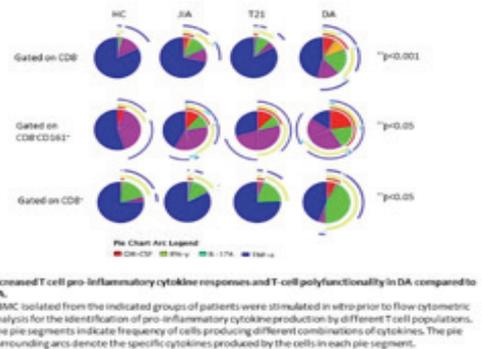
Results

Expansion of IgM-only memory B-cells was demonstrated in DA compared to JIA, paralleled by decreased frequency of transitional B-cells. T-cell responses in DA were characterised by marked functional plasticity, evident by the increased frequency of polyfunctional CD8+ and CD161+ Th cells, positive for TNF-α, IFN-γ, IL-17A, or GM-CSF compared to all other groups. Significant expansion of CXCR3+CCR6+ (Th1/Th17) Tfh cells and CXCR3+CCR6+ Tph cells, paralleled by decreased CXCR3-CCR6- (Th2) Tfh was observed in children with DA compared to HC and T21. Naïve and memory Treg cells were significantly reduced in DA compared to T21, with a significant reduction in the naïve/memory Treg cell ratio. Marked synovial-tissue inflammation with increased T-and B-cell infiltration were demonstrated in children with DA compared to JIA.

Conclusions

DA is more common and more aggressive than JIA. It is characterised by increased T cell plasticity and polyfunctional Th, Tfh and Tph-cell responses, reduced Treg cell frequency and increased synovial-inflammation, which are distinct from JIA and T21.

Figure



(19A137) ABSTRACT 6

ORAL PRESENTATION (SCIENTIFIC)

The role of cellular metabolism in Rheumatoid and Psoriatic Arthritis

Author(s)

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Introduction

Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PsA) share many



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common clinical manifestations, however significant pathogenic differences exist including differential vascular morphology, cellular infiltration and synovial hyperplasia.

#### **Aims/Background**

The aim of this study was to compare the functional and metabolic profiles of RA and PsA synovial fibroblast cells (SFC) and to determine their effect on endothelial cell (EC) function.

#### **Method**

RA and PsA primary SFC were grown to confluence, supernatants were harvested and termed 'conditioned media' (CM). The metabolic profiles of RA and PsA SFC were analysed using the XF96 Extracellular Flux Analyzer. SFC migration and invasion were determined by wound repair and transwell invasion assays. HUVEC were cultured in the presence of RA or PsA SFC-CM (20%). Matrigel tube-formation, wound repair and PBMC adhesion assays were performed on HUVEC. HUVEC cell surface expression of ICAM, VCAM and E-Selectin was assessed by flow-cytometry. Transcriptome analysis was quantified by real-time PCR. Finally, a MSD-multiplex angiogenic assay was performed in RA and PsA SFC supernatants.

#### **Results**

RA SFC displayed increased migratory capacity and invasiveness compared to PsA SFC. A higher oxygen consumption rate (OCR)/extracellular acidification rate (ECAR) ratio were observed in RA SFC. In parallel, IL-6, IL-8 and the glycolytic markers, GLUT1/3, HK2, PKM1/2, PDK2 and LDHA were higher in RA vs PsA SFC ( $p < 0.05$ ). Transcriptome analysis showed strong upregulation of the pro-angiogenic machinery in PsA SFC-CM-primed HUVEC compared to RA SFC-CM. PsA SFC-CM significantly induced HUVEC tube formation, junction formation and segment number compared to RA SFC-CM ( $p < 0.05$ ). Furthermore, PsA SFC-CM induced HUVEC migration, VEGFA, ICAM-1 and MMP3 mRNA expression (all  $p < 0.05$ ). A significant increase in PBMC adhesion, expression of VCAM-1, ICAM-1 and E-Selectin were demonstrated in PsA SFC-CM-primed HUVEC compared to RA SFC-CM (all  $p < 0.05$ ). Finally, VEGF, TSLP, Flt-1 and Tie-2 expression was significantly elevated in PsA SFC-CM compared to RA-SFC-CM ( $p < 0.05$ ).

#### **Conclusions**

Consistent with clinical observations, RASFC have a greater migratory and invasive capacity than PsA SFC. In contrast, the PsA joint microenvironment induces a more pro-angiogenic phenotype than the RA microenvironment. Further understanding of the underlying differential molecular mechanisms in RA and PsA may lead to better treatment strategies.

(19A138) ABSTRACT 7

ORAL PRESENTATION  
(SCIENTIFIC)

### **Distinct monocyte and macrophage inflammatory and bioenergetic profiles in Rheumatoid Arthritis**

#### **Author(s)**

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#### **Introduction**

Monocytes and macrophages play a key role in RA disease progression, however, the diversity and plasticity of cell subsets and their metabolic profile in inflammatory arthritis has yet to be

elucidated.

#### **Aims/Background**

To elucidate the inflammatory and metabolic profiles/function of RA monocytes and macrophages and fully characterise RA synovial tissue macrophage subsets.

#### **Method**

CD14<sup>+</sup> monocytes from RA, Arthralgia and HC bloods were isolated and examined ex-vivo or following differentiation into M1/M2 macrophages. Inflammatory mediators, metabolic markers and transcriptional activity was determined by RT-PCR and western blot, and phagocytosis capacity by OVA-albumin assays. Glycolysis (ECAR) and oxidative phosphorylation (OCR) were quantified by Seahorse-XFE-technology. Single cell synovial-tissue suspensions from RA, PsA and OA biopsies and synovial fluid cells were analysed for macrophage subsets (CD40, CD45, CD64, CD68, CD163, CD206, CD253) by flow cytometry. Double positive CD206<sup>+</sup>CD163<sup>+</sup> vs CD206<sup>-</sup>CD163<sup>-</sup> cells were sorted by FACS Aria Fusion sorter and RNAseq transcriptomic analysis performed.

#### **Results**

RA monocytes are hyperinflammatory, with significantly higher expression of IL-1 $\beta$ , TNF $\alpha$ , IL-6, OSM, CXCL10 and CXCL11 compared to HC (all  $p < 0.05$ ), this profile is maintained in monocyte-derived M1-macrophages and M2 macrophages with impaired phagocytic capacity observed. In parallel, an increase in HIF1 $\alpha$  and PFKFB3 (a key glycolytic enzyme) was observed compared to HC (all  $p < 0.05$ ). Baseline glycolysis ( $p < 0.05$ ), the maximal glycolytic capacity ( $p < 0.05$ ) and the ECAR:OCR ratio were increased in RA CD14<sup>+</sup> monocytes and RA M1 macrophages compared to HC ( $p < 0.05$ ). Interestingly, this pro-hyperinflammatory/metabolic phenotype was also evident in CD14<sup>+</sup> monocytes from arthralgia ACPA+/RF+ subjects. Transcriptional activation of STAT3 induced this hyperinflammatory/metabolic phenotype, with STAT3-inhibition resulting in metabolic reprogramming and resolution of inflammation. A significant enrichment of a dominant double positive CD206<sup>+</sup>CD163<sup>+</sup> compared to CD206<sup>-</sup>CD163<sup>-</sup> macrophages was demonstrated in synovial-tissue versus fluid ( $p < 0.05$ ), with a significant increase in the frequency of CD206<sup>+</sup>CD163<sup>+</sup>CD40<sup>+</sup> macrophages in RA synovial-tissue compared to PsA and OA ( $p < 0.05$ ). Finally, RNAseq revealed differential expression of genes involved in immune activation, cell adhesion and metabolism in CD206<sup>+</sup>CD163<sup>+</sup> vs CD206<sup>-</sup>CD163<sup>-</sup> synovial tissue macrophages.

#### **Conclusions**

This study demonstrates a unique inflammatory and metabolic phenotype of RA monocytes/macrophages, a phenotype that may precede disease onset. Furthermore we have identified, for the first time, enrichment of a dominant transcriptionally distinct macrophage subtype in RA synovial-tissue.

(19A154) ABSTRACT 8

ORAL PRESENTATION  
(SCIENTIFIC)

### **Inhibition of glycolytic pathways induce resolution of Inflammation**

#### **Author(s)**

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#### **Department(s)/Institutions**

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#### **Introduction**

Inflammatory cells require energy to maintain their activation state.



Recent evidence suggests that altered cellular metabolism plays a key role in driving synovial infiltration and invasive mechanisms in RA.

#### Aims/Background

This study examines the role of cellular-metabolism in driving inflammatory pathways in RA and in at-risk of RA subjects (arthralgia).

#### Method

Synovial-tissue and PBMC were obtained from RA, OA, HC and arthralgia (ACPA+/RF+, normal-CRP, no-synovitis). Primary RA synovial fibroblasts (RASFC) RASFC were also obtained. Expression of metabolic-mediators Glut-1,-PFKFB3,-PKM2, pro-inflammatory cytokines (IL-6,-IL-8,-MCP-1) and transcription-factor pSTAT3 and HIF1a were quantified by RT-PCR, western-blot analysis and immunohistology. Synovial-tissue bioenergetics was assessed by real-time Seahorse-XF24-Flux-Analyzer. The effect of metabolic-inhibitors on proinflammatory mediators and transcriptional regulation in RA synovial-explants and RASFC was quantified by RT-PCR, ELISA western-blot and invasion/migration assays.

#### Results

PFKFB3, Glut-1, IL-6, IL-8 and pSTAT3 mRNA expression were significantly increased in synovial-tissue and PBMC from RA vs OA/-HC. Interestingly, increased expression of PFKFB3, IL-6,-IL-8,-MCP-1 were also observed in arthralgia vs OA/-HC. PFKFB3 and Glut-1 were localised in the synovial vascular and lining-layer regions, levels increasing in a stepwise-progression from OA to arthralgia to RA. This was paralleled by real-time analysis of synovial-tissue explants demonstrating a shift in the bioenergetic-profile where an increase in ATP-consumption and the glycolytic/oxidative-phosphorylation ratio was demonstrated in RA vs arthralgia vs OA. Addition of glycolytic-inhibitors to RASFC and RA synovial-explant cultures significantly decreased transcriptional activation of pSTAT3 and HIF1a, secretion of pro-inflammatory cytokines (IL-6,-IL-8,-MCP-1), paralleled by inhibition of synovial fibroblast invasive and migrative mechanisms.

#### Conclusions

This study demonstrates a switch in the metabolic-profile in favour of glycolysis in RA synovial-tissue and cells, an effect also observed in arthralgia subjects suggesting that cells may already be primed pre-onset of RA. Glycolytic-inhibitors promoted resolution of inflammation suggesting potential new therapeutic strategies.

#### (19A102) ABSTRACT 9

#### PREMIER POSTER 1

### A Systematic Review of the Irish Osteoporotic Vertebral Fracture Literature and the Diagnostic Gap in Patients Admitted with Hip Fracture

#### Author(s)

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#### Department(s)/Institutions

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2. School of Medicine, National University of Ireland, Galway
3. Department of Trauma and Orthopaedic Surgery, Galway University Hospitals
4. Department of Radiology, Galway University Hospitals

#### Introduction:

Vertebral fractures (VF) are the most common osteoporotic fracture. They are associated with significant morbidity, mortality and are an important predictor of future fractures. The epidemiology of VF in Ireland is limited and a greater understanding of their scale and impact is needed.

#### Methods:

We conducted a systematic review of the Irish osteoporotic VF literature in accordance with the PRISMA guidelines. We also assessed the prevalence of VF on CTPA in patients admitted with hip fractures to Galway University Hospitals using a blinded assessor who graded fractures by Genant classification. Subsequently the proportion that were reported by the original radiologist was determined. Discharge summaries and prescriptions were reviewed for osteoporosis diagnoses and appropriate treatment.

Results: 21 studies met the inclusion criteria with data on 191,903 patients with fractures. There was significant heterogeneity in the study designs and outcome measures including review of hospital admission claims data, surgical and medical interventions and the impact of a fracture liaison service. Using a prospective hip fracture database, 225/2122 patients had a CTPA available for analysis. 40% (90) of patients had a VF present on CTPA. Only 1 in 5 VF were previously reported. 24% had osteoporosis treatment recorded in discharge summaries or prescriptions.

#### Conclusions:

There is a large deficit in studies addressing the epidemiology of VF in Ireland which reflects the current situation of osteoporotic spine care in Ireland. A significant proportion of these fractures remain undiagnosed and are not captured. Improved reporting is necessary to trigger osteoporosis assessments and initiate treatment.

#### (19A104) ABSTRACT 10

#### PREMIER POSTER 2

### Advice to males with rheumatic diseases on non-biologic disease modifying anti-rheumatic (DMARD) therapy planning to conceive – A regional audit

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#### Introduction

There are multiple male patients with rheumatic diseases who are of the appropriate age to conceive, and who are on non-biologic DMARD therapy. There is limited evidence relating to the impact of these therapies upon peri-conception paternal exposure and male fertility. The British Society of Rheumatology have issued some recommendations in their BSR and BHRP guideline on 'prescribing drugs in pregnancy and breastfeeding—Part I: standard and biologic disease-modifying anti-rheumatic drugs and corticosteroids' (published 10th January 2016), but not all medications have been included, and the evidence for these recommendations is limited.

#### Aims/Background

To ascertain the current advice being given within the rheumatology departments in Northern Ireland to males with rheumatic diseases on non-biologic DMARD therapy who are planning to conceive.

#### Method

An anonymous questionnaire was developed listing the common non-biologic DMARDs being used to treat rheumatic diseases. Respondents were asked to indicate if, and for how long, they asked male patients to discontinue these non-biologic DMARDs when planning to conceive. The questionnaire was distributed to Consultant Rheumatologists and Rheumatology Specialty Trainees working in Northern Ireland in October 2018.

#### Results

There were 18 respondents, (response rate 54%). Below are tables summarising the responses for each of the non-biologic DMARDs listed in the questionnaire. Table 1 shows the percentage of respondents who recommend that the non-biologic DMARDs listed



should be discontinued by male patients planning to conceive. Table 2 shows the duration of time that the respondents recommended discontinuing the non-biologic DMARDs prior to conception in males if advised to discontinue.

**Conclusions**

These results indicate that there is a variation in advice being given to male patients on non-biologic DMARDs who are planning to conceive. There is limited evidence on which to base current advice and guidance. More research into this area is needed. Registration of the relevant pregnancies with the Organization of Teratology Information Specialists (OTIS) will help to gather better evidence for the future. This will enable more informed decision making to be facilitated.

Figure

Table 1: DMARD	% Continue	% Discontinue
Hydroxychloroquine	100%	
Methotrexate	45%	55%
Sulphasalazine	75%	25%
Leflunomide	20%	80%
Azathioprine	87.5%	12.5%
Cyclosporine	40%	60%
Tacrolimus	33%	67%
Mycophenolate Mofetil	13.3%	86.7%
Cyclophosphamide	7%	93%

Figure

Table 2: DMARD	% Discontinue 0-3 months	% Discontinue 3-6 months	% Discontinue 6-12 months
Methotrexate	62%	38%	
Sulphasalazine	75%	25%	
Leflunomide	67% (or washout)	16.5%	16.5%
Azathioprine		100%	
Cyclosporine	67%	33%	
Tacrolimus	50%	50%	
Mycophenolate Mofetil	37.5%	50%	12.5%
Cyclophosphamide	27.2%	9.2%	63.6%

have shown many of these cells have properties of Tissue resident memory (TRM) T cells, a recently defined subset of CD8+ T cells which remain resident within tissues.

**Aims/Background**

We sought to identify the presence and frequency of Tc17 /TRM cells and other cytokine expressing cells within the joints of patients with EIA.

**Method**

Patients with EIA had synovial fluid samples collected after giving informed consent in the Guy’s Hospital Rheumatology clinic. Synovial fluid mononuclear cells (SFMC) were immediately isolated and cryopreserved. For FACs analysis cells were thawed and stimulated for 3 hours with PMA, Ionomycin and Golgistop, and then stained for CD-3, CD-14, CD-4, CD-8 and cytokine expression (IL-17, IFN-g and TNF-a). 12 samples also had extracellular stain for the presence of TRM cells (CD69+CD103+ CD8+ T cells). Samples were all acquired on a BD Canto Flow Cytometer and analysis was completed using FlowJo and PRISM.

**Results**

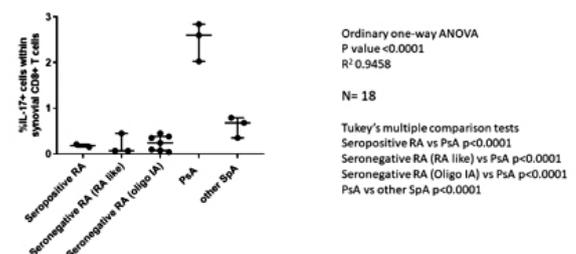
We recruited 18 patients with final diagnoses of Seropositive RA (2), Seronegative polyarthritis like RA (3), Seronegative oligo-IA (7), PsA (3), other Spondylo-arthropathy (SpA)/ Reactive Arthritis (REA) (3). Synovial fluid Tc17 cell frequencies showed statistical significant differences between all groups (ordinary one-way ANOVA p <0.0001), with the highest frequencies seen in early PsA. Secondary analysis using Tukey’s multiple comparison tests showed significant differences between seropositive RA and PsA (p <0.0001), seronegative RA and PsA (RA like p <0.0001, oligo IA p <0.0001) and PsA and SpA (p <0.0001). There was no difference in 12 patients tested for TRM cell frequencies. Th17 cells were frequently found with no significant difference between sub-groups. Tc1 had high frequencies again with no differences across groups.

**Conclusions**

This preliminary study of 18 patients with EIA shows that the Tc17 cells are clearly found in SF of patients with early PsA and those with other SpA/REA. The less well defined oligo EIA and RA have very low Tc17 levels. SF TRM cells have only previously been described in Juvenile Idiopathic Arthritis. These data show that TRM cells are present in the joints of most patients with EIA. These very preliminary data will need increased numbers to identify any potential role these cells may play in persistent inflammatory arthritis.

Figure

Tc17 frequencies across disease groups



(19A106) ABSTRACT 11

PREMIER POSTER 3

**IL-17A expressing T cells and Tissue Resident Memory T cells in Early Inflammatory Arthritis**

**Author(s)**

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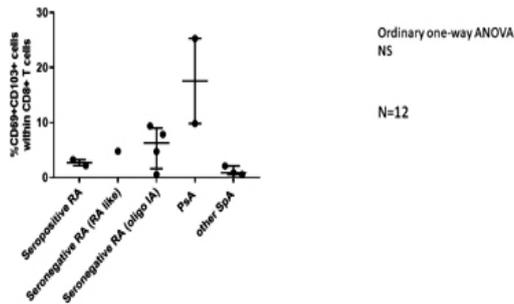
**Introduction**

Early inflammatory arthritis (EIA), classically defined as >6 weeks and ≤ 12 months duration is often difficult to diagnose and classify. Our group has previously reported IL-17+CD8+ T (Tc17) cells within the joints of patients with Psoriatic Arthritis (PsA). More recently we



Figure

### T<sub>RM</sub> T cell frequencies across disease groups



(19A107) ABSTRACT 12

PREMIER POSTER 4

### Understanding Patients' Perception of Symptoms with Psoriasis and Psoriatic Arthritis

#### Author(s)

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#### Introduction

Psoriatic disease includes both psoriasis (PS) and psoriatic arthritis (PsA), which typically affect both the skin and joints in addition to systemic features. These diseases are managed jointly between Rheumatology and Dermatology departments using a myriad of treatment options. Due to the wide range of symptoms affecting these diseases, it can be a challenge for the clinician to understand the importance of certain symptoms from a patient perspective, which can have implications in terms of treatment priorities and disease severity.

#### Aims/Background

To improve understanding of patients' perception of their symptoms to aid assessment of disease severity, ongoing level of disease activity and need for further treatment in the setting of PS and PsA.

#### Method

This was an opt-in cross sectional study of patients with PS and PsA attending the Rheumatology and Dermatology outpatient departments at University Hospital Waterford. A survey was designed to gather patient perception of their symptoms. The focus of the surveys was on symptoms commonly associated with both PS and PsA. Symptoms were ranked from most to least problematic in terms of overall skin and joint features.

#### Results

Fifty-four patients completed the surveys, of which 29 patients had PsA and 25 had PS. The average duration of disease was 16.4 years with most patients currently taking a combination of biologic and topical treatments. Of the patients with PsA, joint pain was considered the most problematic while flaking of skin the least problematic. Of the PsA patients with skin disease, they tended to have more severe redness and nail problems than PS patients. For PS pruritis was ranked as the most problematic while painful skin was the least troublesome. Very few PS patients reported eye symptoms(8%) while over 70% reported fatigue. The PsA patients rarely encountered difficulty at work due to their disease, however a large proportion had difficulty with social encounters and sleep.

#### Conclusions

This study provides insight into symptoms which patients consider of high importance. Improved awareness and screening for these symptoms would aid clinician assessment of disease severity and the functional impact on activities of daily living thus guiding the need for further treatment.

(19A123) ABSTRACT 13

PREMIER POSTER 5

### Protein Biomarkers to Differentiate Psoriatic Arthritis from Psoriasis

#### Author(s)

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#### Department(s)/Institutions

The Conway Institute, UCD; St. Vincent's University Hospital

#### Introduction

In the BIOMarkers of COMorbidities (BIOCOM) in Psoriasis (Pso) study we aim to identify clinical, genetic and protein biomarker features associated with the development of psoriatic arthritis (PsA), in patients with Pso. Pso usually precedes the development of PsA with an average interval of 10 years. Thus, patients with Pso are an ideal group in which to study the early events in the evolution to PsA.

#### Aims/Background

To use a targeted proteomics approach to identify serum proteins which can predict the development of PsA in patients with Pso. We initially sought to identify serum proteins capable of discriminating between patients with Pso only and patients with established PsA.

#### Method

30 patients with Pso and 30 patients with established PsA were selected from the BIOCOM-Pso database. Serum samples from these patients were digested using a standard operating protocol (SOP). Once digested, a targeted proteomics approach using liquid chromatography – mass spectrometry (LC-MS) and a multiple reaction monitoring (MRM) assay called PAPRICA was used to measure candidate biomarker proteins. These 206 proteins (423 peptides) were previously identified as being potential biomarkers in a number of different inflammatory rheumatological conditions.

#### Results

The demographics of the 2 patient groups are shown in Table 1. The initial results revealed that the application of the PAPRICA method to the BIOCOM-Pso samples resulted in a dataset in which 275 of the 423 PAPRICA peptides could be reliably measured (CV Area < 20%; Signal to Noise ratio > 5; Library Dot Product > 0.8). Targeted proteomics data from the PsA and Pso patients was subjected to univariate and multivariate analysis. Univariate analysis revealed five peptides with a p value < 0.05, however none of these remained significant after Bonferroni correction for multiple comparisons. Multivariate analysis was unable to discriminate between PsA and Pso.

#### Conclusions

Analysis of the 206 biomarker proteins in the PAPRICA method, in patients with PsA and Pso, did not reveal peptides (proteins) that were statistically different between these two groups. The next steps will include supplementing the PAPRICA method with additional biomarkers including proteins that may be identified in an unbiased proteome wide screen of PsA vs Pso serum samples.



Figure

Patient Group	Pso	PsA
Age, mean +/- SD years	41.1 +/- 14.6	50.3 +/- 10.6
Male Sex, number (%)	20 (66.7)	21 (70)
Duration of Pso, mean +/- SD years	6.5 +/- 2.9	23.3 +/- 12.1
Duration of PsA, mean +/- SD years		14.8 +/- 10.1
PASI, mean +/- SD	8.1 +/- 3.7	2.8 +/- 2.7
CPDAI, mean		4.4

(19A158) ABSTRACT 14

PREMIER POSTER 6

### Investigation Into rs26232 Genotype Association with Susceptibility and Severity of Rheumatoid Arthritis

#### Author(s)

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#### Department(s)/Institutions

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#### Introduction

The single nucleotide variant rs26232 has been associated with both the susceptibility to, and severity of, rheumatoid arthritis (RA). An allele dose response between rs26232 and radiological damage has been observed, with the T allele being protective against disease severity. rs26232 is situated in the first intron of C5orf30, a negative regulator of tissue damage and inflammation in RA.

#### Aims/Background

This study aims to elucidate the mechanism by which rs26232 may mediate disease severity and determine the genotype-phenotype association of rs26232 in rheumatoid arthritis synovial fibroblasts (RASf).

#### Method

RASf were derived from knee biopsies of RA patients taken at arthroscopy (n=33). Matrigel-coated Boyden transwell chambers were used to measure invasion. Wound healing (scratch assays) were used to measure migration. Proliferation was measured via crystal violet staining of fixed RASf. Intracellular cytokine staining and cell surface markers were measured via flow cytometry. Secreted cytokines were measured using ELISA. rs26232 genotype was determined by PCR genotyping assay with allelic discrimination analysis. Quantitative real-time PCR was used to measure gene expression.

#### Results

rs26232 is associated with invasion of RASfs, with the CC genotype showing increased invasion (p=0.021). The CC genotype also showed higher expression of the adhesion molecules ICAM1 (p=0.001), VCAM (p=0.05) and IP10/CXCL10 (p=0.01). No association was found between rs26232 genotype and migration, proliferation, or expression of MMP3, TIMP3, MCP1 or MIP1. There was no differential expression of C5orf30 in rs26232 genotype groups. In silico analysis of the region in which rs26232 is located identified a DNase Hypersensitivity cluster. Three genes within this region (PAM, PPIP5K2 and EIF3KP1) show expression quantitative trait loci (eQTL) association with rs26232. These genes also contain the active enhancer mark H3K27Ac. GIN1, also within this region, is neither an eQTL nor contains H3K27Ac. qPCR analysis of PAM, PPIP5K2 and GIN1 gene expression showed an association between rs26232 genotype and PAM gene expression (p=0.05).

#### Conclusions

The CC genotype of rs26232 is associated with both increased invasiveness of RASfs and increased adhesion markers. rs26232

does not mediate its affect via its nearest gene, C5orf30. Gene expression analysis of nearby genes suggests that PAM may be responsible for the phenotypes associated with rs26232 genotype.

(19A171) ABSTRACT 15

PREMIER POSTER 7

### Real-life single-centre experience of Tocilizumab-associated neutropenia in children with juvenile idiopathic arthritis (JIA)

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#### Introduction

Tocilizumab, approved for treatment of children with Systemic-onset-JIA (SoJIA) and polyarticular-JIA (pJIA) is efficacious and well-tolerated. Transient neutropenia is a side-effect of treatment.

#### Aims/Background

Retrospective chart review of children treated with Tocilizumab to report on Tocilizumab-associated neutropenic episodes.

#### Method

Retrospective review of patients receiving Tocilizumab (January 2010-January 2019). Patients with extended-oligoarticular-JIA (ExO-JIA), pJIA and SoJIA reviewed in more detail to ascertain frequency of neutropenia and related-factors. For analysis, ExO-JIA and pJIA were combined to create an ExO/pJIA group. Neutropenia was defined as neutrophils <1.5 and severe-neutropenia as neutrophils <1.0. Statistical analysis was performed using the Mann-Whitney-U and Chi-Square tests.

#### Results

Sixty-eight children (60% female) attending the rheumatology department at GOSH are receiving Tocilizumab. Of these, 53 (78%) have a diagnosis of ExO-JIA (n=10), pJIA (n=12) or SoJIA (n=31). Disease duration pre-commencement of Tocilizumab was 2.9years (0.1-11). Children with SoJIA were commenced on Tocilizumab significantly (p2 episodes) occurred in 38% (20/53) and was significantly more common in SoJIA (p<0.05). All children with ExO/pJIA experienced a total of 2-3 neutropenic-episodes, significantly less (p<0.05) than the recurrence-rate in children with SoJIA (average 7 episodes, range 2-17).

Severe neutropenia occurred in 65% (n=13) and was significantly (p<0.001) more frequent in SoJIA (n=11, 85%). In those with recurrent neutropenia, no significant correlation was identified between risk of neutropenia and interval between doses, dose (mg/kg) received, concurrent Methotrexate, duration on Tocilizumab or number of alternative treatments received pre-Tocilizumab.

Seventeen-children (32%) taking Tocilizumab had a documented infection. No relationship between neutropenia and risk of infection was identified.

#### Conclusions

Tocilizumab-associated neutropenia is more frequent, severe and recurrent in SoJIA. Neutropenia can occur at any stage in the treatment course. Clinicians should consider long-term blood-monitoring pre-Tocilizumab, especially for those with SoJIA.

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Professor David Kane



Dr Bryan Whelan, Dr Paul O'Connell and Dr John Ryan



(19A178) ABSTRACT 16

PREMIER POSTER 8

**Initial Analysis of Prescribing Trends on PCRS Hub\* (\*At ISR, updated quarterly data will be presented from June 1st to September 1st 2019)**

**Author(s)**

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**Department(s)/Institutions**

Tallaght University Hospital (1) & HSE National Clinical Programme for Rheumatology (2)

**Introduction**

The 'High Tech Prescription Hub' (HTPH) was established on June 1st for prescribing biologic DMARDs. The HTPH identifies 'Best Value Biologics' (BVB, lowest cost biosimilar) to the prescriber for adalimumab and etanercept to promote initiation and switching.

**Aims/Background**

Data from the HTPH on biologic prescribing practices in Ireland is presented.

**Method**

All prescriptions issued by rheumatology, gastroenterology and dermatology on the HTPH from June 1st to July 15th were analysed by therapeutic agent, specialities and hospital groups. \*

**Results**

Of 40 individual hospital sites in Ireland, registration rates for HTPH were as follows: rheumatologists 33/40, gastroenterologists 16/40, dermatologists 10/40. Of the 7 sites with no rheumatologist registered, the local rheumatologist was already registered at another hospital site, giving 100% registration for rheumatology.

2247 HTPH biologic prescriptions were issued between June 1st and July 15th - 1977 (88%) by rheumatology, 262 (11%) by dermatology and 8 by gastroenterology (<1%). For Rheumatology prescriptions, South/Southwest Hospital Group (SSWHG) accounted for 908 (46%) prescriptions followed by Private Hospitals (PH) with 448 (22.7%), Dublin Midlands Hospital Group (DMHG) with 279 (14%), Saolta University Healthcare Group (SUHG) with 216 (11%), University Limerick Hospitals Group (ULHG) with 75 (4%) and Ireland East Hospital Group (IEHG) with 51 (2.6%).

Adalimumab was prescribed for 597 patients in rheumatology (30% of all rheumatology prescriptions). Humira was prescribed in 473 (79%) cases, Imraldi in 76 (12.7%), Amgevita in 43 (7.2%) and Hulio in 5 (0.83%) cases. Etanercept was prescribed in 602 rheumatology patients (31% of all rheumatology prescriptions) with 150 (25%) being prescribed Benepali.

In all, 290 patients were switched to, or initiated on, a BVB: rheumatology = 221 (76.2%), dermatology = 69 (23.7%) and gastroenterology = 0. BVB prescriptions in rheumatology are as follows: DMHG 92 (41.6%), SSWHG 48 (22%), PH 45 (20.4%), IEHG 22 (10%), SUHG 9 (4%), ULHG 5 (2.3%).

**Conclusions**

Adalimumab and etanercept comprised almost 2/3 of all biologic prescriptions in rheumatology. Uptake of biosimilars since June 1st 2019 is 22% with biosimilar prescription rates varying between hospital groups and specialties. Rheumatology accounts for the vast majority of biosimilar prescriptions in the initial period of HTPH operation.

High Tech Prescriptions for Dermatology, Gastroenterology & Rheumatology generated on the PCRS Hub 1<sup>st</sup> June - 15<sup>th</sup> July 2019

Hospital Group	Rheumatology				Dermatology		Gastroenterology	
	Total	Adalimumab	Etanercept	BVB	Total	BVB	Total	BVB
Dublin Midlands Hospital Group	279	71	102	92				
Ireland East Hospital Group	51	23	19	22	7	5		
Private	448	132	162	45				
Saolta University Health Care Group	216	79	72	9	103	21		
South/South West Hospital Group	908	262	218	48	152	43	2	
University Limerick Hospitals Group	75	28	29	5			6	
<b>Overall Total</b>	<b>1977</b>	<b>597</b>	<b>602</b>	<b>221</b>	<b>262</b>	<b>69</b>	<b>8</b>	<b>0</b>

Figure

(19A184) ABSTRACT 17

PREMIER POSTER 9

**Despite advances in therapeutics, patients with rheumatoid arthritis continue to exhibit joint destruction**

**Author(s)**

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**Introduction**

Whether the presence of erosive disease on plain film radiography represents an important, measurable outcome in rheumatoid arthritis (RA) in the modern era of therapeutics, has become controversial. Many experience none or little joint damage appreciably by radiography, and fewer experience functional limitations as a result of these observations on radiographs. Nevertheless, several imaging modalities have been shown to accurately identify joint destruction.

**Aims/Background**

How often, in the current era of therapeutics for RA, do patients go on to develop erosive disease, outside of clinical trials, is poorly reported. We sought to examine the prevalence of progression to erosive disease those diagnosed treated for RA in the current era have.

**Method**

77 consecutive patients with RA were followed and index and follow up radiographs were examined for the presence or absence of erosions on plain film radiographs of hands and feet, at index and follow up.

**Results**

34/77 (44.1%) had evidence of erosive disease at most recent follow up imaging. 8/34 (23.5%) of these patients had erosive disease on their index radiographs. 26/34 (76.5%) had evidence of the development of erosive disease, since their index radiographs.

Higher CRP's were statistically significantly associated with the presence of erosions (p=0.03). All other comparators, including disease duration, DAS28-CRP or ESR, serology profile, or smoking status were not significant.

**Conclusions**

Patients with RA commonly continue to develop erosive disease, despite advances in therapeutics. More research is needed to determine the significance of the ongoing development of erosive disease, despite improved clinical outcomes.

(19A191) ABSTRACT 18

PREMIER POSTER 10

**Breaking bad: Reporting of vertebral fragility fractures and the impact to management of bone health**

**Author(s)**

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**Introduction**

Vertebral fragility fracture (VFF) is the most common osteoporotic fracture and a strong predictor for future vertebral fracture(s) and/or hip fracture. A clear reporting of VFF by radiologists offers ample opportunity for early diagnosis and appropriate management of osteoporosis among treating physicians.

**Aims/Background**

The objectives of this study were two-fold; to evaluate 1) the reporting of VFF by radiologists at one of the largest acute hospitals in southern Ireland 2) the management of osteoporosis (adherence to screening for secondary causes and commencement/switching of anti-resorptive therapy accordingly) for patients with VFF.

**Method**

We conducted a retrospective cross sectional study involving all



patients (n=199) who attended our specialist rheumatology outpatient clinics at University Hospital Kerry during the month of November 2018. Patients who previously had undergone plain radiography of the spine (PRS) in the previous 5 years were identified and reassessed for evidence of VFFs. Basic demographic, drug history, clarification of fragility fracture and previous related trauma, investigations for secondary causes of osteoporosis, and treatment received for osteoporosis were documented.

**Results**

73 of the 199 patients had undergone previous PRS, 9 of which had evidence for VFFs. Only two patients (22.2%) were reported as having vertebral “fractures”, while 7 others had different terms used to describe the fracture(s)-2 patients with “wedging”, 1 with “compression”, 2 with “loss of height” and 2 with “collapse”. All (2 patients; 100%) with VFF reported as “fracture” had complete clarification of VFF, secondary osteoporotic work-up and treated with anti-resorptive therapy accordingly. Among the other 7 patients with VFFs but not reported as having “fracture”, 1 patient had concomitant report of “osteoporotic” bones and had complete management for osteoporosis. 4 patients had concomitant report of “osteopenia”, 3 (75%) of which received complete management for osteoporosis; while only 50% (1 patient) of the 2 remaining patients without further description of bone density received appropriate management. Further 6 patients with non-VFF were reported to have reduced bone density (1 reported as “osteoporotic” bones; 5 as “osteopenic” bones). Only one of them (16.7%) had further work-up, evaluation and management for osteoporosis.

**Conclusions**

Clear radiological report of PRS with VFFs using the word “fracture” is a strong predictor for appropriate management of bone health. It is essential that other terms used to describe VFFs such as “wedging”, “compression”, “loss of height” and “collapse” not to be used alone without the concomitant use of the word “fracture”.

(19A105) ABSTRACT 19

REGULAR POSTER 11

**Advice to males with rheumatic diseases on biologic disease modifying anti-rheumatic (DMARD) therapy planning to conceive – A regional audit**

**Author(s)**

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**Introduction**

There are multiple male patients with rheumatic diseases who are of the appropriate age to conceive, and who are on biologic DMARD therapy. There is limited evidence relating to the impact of these therapies upon peri-conception paternal exposure and male fertility. The British Society of Rheumatology have issued some recommendations in their BSR and BHPR guideline on ‘prescribing drugs in pregnancy and breastfeeding—Part I: standard and biologic disease-modifying anti-rheumatic drugs and corticosteroids’ (published 10th January 2016), but not all medications have been included, and the evidence for these recommendations is limited.

**Aims/Background**

To ascertain the current advice being given within the rheumatology departments in Northern Ireland to males with rheumatic diseases on biologic DMARD therapy who are planning to conceive.

**Method**

An anonymous questionnaire was developed listing the common biologic DMARDs being used to treat rheumatic diseases. Respondents were asked to indicate if, and for how long, they asked male patients to discontinue these non-biologic DMARDs

when planning to conceive. The questionnaire was distributed to Consultant Rheumatologists and Rheumatology Specialty Trainees working in Northern Ireland in October 2018.

**Results**

There were 18 respondents, (response rate 54%). Below are tables summarising the responses for each of the biologic DMARDs listed in the questionnaire. Table 1 shows the percentage of respondents who recommend that the biologic DMARDs listed should be discontinued by male patients planning to conceive. Table 2 shows the duration of time that the respondents recommended discontinuing the biologic DMARDs prior to conception in males if advised to discontinue.

**Conclusions**

These results indicate that there is a variation in advice being given to male patients on biologic DMARDs who are planning to conceive. There is limited evidence on which to base current advice and guidance. More research into this area is needed. Registration of the relevant pregnancies with the Organization of Teratology Information Specialists (OTIS) will help to gather better evidence for the future. This will enable more informed decision making to be facilitated.

Figure

Table 2: Biologic DMARD	% Discontinue 0-3 months	% Discontinue 3-6 months	% Discontinue 6-12 months
Infliximab	100%		
Etanercept	100%		
Adalimumab	100%		
Certolizumab Pegol	100%		
Golimumab	50%	50%	
Rituximab	25%	75%	
Tocilizumab	50%	50%	
Anakinra	100%		
Abatacept	67%	33%	
Belimumab	33%	67%	
Secukinumab	33%	67%	
Ustekinumab	33%	67%	

Figure

Table 2: Biologic DMARD	% Discontinue 0-3 months	% Discontinue 3-6 months	% Discontinue 6-12 months
Infliximab	100%		
Etanercept	100%		
Adalimumab	100%		
Certolizumab Pegol	100%		
Golimumab	50%	50%	
Rituximab	25%	75%	
Tocilizumab	50%	50%	
Anakinra	100%		
Abatacept	67%	33%	
Belimumab	33%	67%	
Secukinumab	33%	67%	
Ustekinumab	33%	67%	



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**Dosage and Administration:** *Adults with rheumatoid arthritis:* Recommended initial dose is 7.5mg per week. Weekly dose of 25mg should not be exceeded. Doses exceeding 20mg/week are associated with significant increase in toxicity. Response to treatment expected after approximately 4 – 8 weeks. Upon achieving therapeutically desired result, reduce dose gradually to lowest effective maintenance dose. *Children and adolescents below 16 years with polyarthritic forms of juvenile idiopathic arthritis:* Children with body surface area below 0.75m<sup>2</sup> cannot be treated with this product. Recommended dose 10 - 15mg/m<sup>2</sup> body surface area (BSA) **once weekly** by subcutaneous injection. Weekly dosage may be increased to 20mg/m<sup>2</sup> BSA **once weekly**. Increase monitoring frequency if dose increased. Refer patients to rheumatology specialist in the treatment of children/adolescents. Use in children < 3 years of age not recommended. *Psoriasis vulgaris and psoriatic arthritis:* Administer test dose of 5 – 10mg parenterally, one week prior to therapy to detect idiosyncratic adverse reactions. Recommended initial dose 7.5mg **once weekly** subcutaneously. Increase dose gradually. Do not exceed weekly dose of 25mg. Doses exceeding 20mg per week are associated with significant increase in toxicity. Response to treatment expected after approximately 2 – 6 weeks. Upon achieving therapeutically desired result, reduce dose gradually to lowest effective maintenance dose. Increase dose as necessary but do not exceed maximum recommended weekly dose of 25mg. Exceptionally a higher dose might be clinically justified, but should not exceed a maximum weekly dose of 30mg. *Crohn's Disease:* Induction treatment 25mg/week subcutaneously. Response to treatment expected after approximately 8 to 12 weeks. Maintenance treatment 15mg/week subcutaneously. *Renal impairment:* Use with caution. See SPC for dose adjustments based on creatinine clearance. *Hepatic impairment:* Use with great caution, if at all, in patients with significant current or previous liver disease, especially if due to alcohol. If bilirubin is > 5mg/dl (85.5 μmol/l), methotrexate is contraindicated. *Elderly patients:* Consider dose reduction. *Third distribution space (pleural effusions, ascites):* Half-life can be prolonged, dose reduction or discontinuation may be required. **Contraindications:** Hypersensitivity to methotrexate or any of the excipients. Severe liver impairment. Alcohol abuse. Severe renal impairment (creatinine clearance less than 30 ml/min). Pre-existing blood dyscrasias. Serious, acute or chronic infections. Ulcers of oral cavity and known active gastrointestinal ulcer disease. Pregnancy, breast-feeding. Concurrent vaccination with live vaccines. **Warnings and Precautions:** Clearly inform patients that therapy should be administered **once a week**, not every day. Supervise patients so that signs of possible toxic effects or adverse reactions are detected and evaluated with minimal delay. Treatment should be initiated and supervised by physicians with knowledge and experience in use of antimetabolite therapy. Possibility of severe/fatal toxic reactions, patients should be fully informed by physician of risks and recommended safety measures. *Before beginning or reinstating treatment:* Complete blood count with differential and

platelets, liver enzymes, bilirubin, serum albumin, chest x-ray and renal function tests. If clinically indicated, exclude tuberculosis and hepatitis. *During therapy (at least once a month during the first six months and every three months thereafter):* Examine mouth and throat for mucosal changes. Complete blood count with differential and platelets. Profound drop in white-cell or platelet counts indicates immediate withdrawal of treatment and appropriate supportive therapy. Advise patients to report signs and symptoms of infection. Monitor patients taking haematotoxic medicinal products (e.g. leflunomide) closely with blood count and platelets. Liver function tests: Do not start treatment if abnormality of liver function tests or liver biopsy present. Stop treatment if abnormalities develop. Treatment may be recommenced if liver function returns to normal. Evaluate need for liver biopsy in psoriasis therapy. Temporary increases in transaminases have been reported. Consider dose reduction or discontinuation in the case of a constant increase in liver-related enzymes. Additional hepatotoxic medicinal products should not be taken unless clearly necessary and consumption of alcohol should be avoided. Monitor liver enzymes closely in patients taking other hepatotoxic products. The same should be taken into account with the simultaneous administration of haematotoxic products. Monitor renal function. Where renal function may be compromised (e.g. the elderly), monitor more frequently particularly when concomitant medicinal products affect the elimination of methotrexate, cause kidney damage or can lead to impairment of blood formation. Dehydration may also intensify methotrexate toxicity. Respiratory system: Be alert for symptoms of lung function impairment. Pulmonary effects require quick diagnosis and discontinuation of methotrexate. Pulmonary symptoms (especially dry non-productive cough) or a non-specific pneumonitis occurring during methotrexate therapy may be indicative of a potentially dangerous lesion and require interruption of treatment and careful investigation. Acute or chronic interstitial pneumonitis, often associated with blood eosinophilia may occur and deaths have been reported. This lesion can occur at all dosages. Pulmonary alveolar haemorrhage has been reported with methotrexate used in rheumatologic and related indications. This event may be associated with vasculitis and other comorbidities. Prompt investigations should be considered when pulmonary alveolar haemorrhage is suspected to confirm the diagnosis. Methotrexate may impair response to vaccination and affect result of immunological tests. Particular caution needed in presence of inactive, chronic infections (e.g. herpes zoster, tuberculosis, hepatitis B or C). Vaccination using live vaccines must not be performed. Malignant lymphomas may occur in which case therapy must be discontinued. Concomitant administration of folate antagonists has been reported to cause acute megaloblastic pancytopenia. Radiation induced dermatitis and sun-burn can reappear (recall-reaction). Psoriatic lesions can exacerbate during UV-irradiation and simultaneous administration of methotrexate. Methotrexate elimination is reduced in patients with a third distribution space (ascites, pleural effusions) requiring careful monitoring for toxicity and dose reduction or discontinuation of methotrexate. Pleural effusions and ascites should be drained prior to initiation of methotrexate. Diarrhoea and ulcerative stomatitis require interruption of therapy. Products containing folic acid, folic acid or derivatives may decrease effectiveness. Treatment of psoriasis with methotrexate should be restricted to severe recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and only when diagnosis established by biopsy and/or after dermatological consultation. Encephalopathy / Leukoencephalopathy have been reported in oncologic patients. Methotrexate has been reported to cause oligospermia, menstrual dysfunction and amenorrhoea in humans, during and for a short period after cessation of therapy and to cause impaired fertility during its administration. These effects appear to be reversible on discontinuing therapy. The absence of pregnancy should be

confirmed before methotrexate is administered. Contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free". Methotrexate has minor or moderate influence on ability to drive and use machines. **Pregnancy and Lactation:** Methotrexate is teratogenic. Contraindicated in pregnancy and lactation. It has been reported that methotrexate treatment could lead to abortion. Women getting pregnant during therapy should receive medical counselling about risk of adverse reactions for the child. Effective contraception (women and men) is required during treatment and for at least 6 months thereafter. **Adverse events include: Adverse events which could be considered serious include:** Common: Leukopenia, thrombopenia, pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia, Uncommon: Pharyngitis, pancytopenia, precipitation of diabetes mellitus, pancreatitis, cirrhosis, fibrosis and fatty degeneration of the liver, renal impairment, gastrointestinal ulcers and bleeding. Rare: Pericarditis, pericardial effusion, pericardial tamponade, thromboembolic events, pulmonary fibrosis, pneumocystis carini pneumonia, acute hepatitis, renal failure, anuria, anaphylactic shock, allergic vasculitis, conjunctivitis, sepsis, hypogammaglobulinaemia. Very rare: Acute aseptic meningitis, lymphoma, agranulocytosis, convulsions, paralysis, retinopathy, haematemesis, toxic megacolon, hepatic failure, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), lymphoproliferative disorders, bone marrow suppression. **Frequency unknown:** Pulmonary toxicity, pulmonary alveolar haemorrhage, hepatotoxicity, renal toxicity, neurotoxicity, leukoencephalopathy, encephalopathy, osteonecrosis of jaw (secondary to lymphoproliferative disorders). **Other Very Common adverse events:** Stomatitis, dyspepsia, nausea, loss of appetite, abdominal pain, abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin). **Other Common adverse events:** Anaemia, headache, tiredness, drowsiness, oral ulcers, diarrhoea, exanthema, erythema, pruritus. See SPC for details of other adverse events. **Shelf Life:** 24 months. **Pack size:** 7.5mg/0.15ml; 10mg/0.20ml; 12.5mg/0.25ml; 15mg/0.30ml; 17.5mg/0.35ml; 20mg/0.40ml; 22.5mg/0.45ml; 25mg/0.50ml; 27.5mg/0.55ml; 30mg/0.60ml. **Marketing Authorisation Holder (MAH):** Accord Healthcare Ireland Limited, Euro House, Euro Business Park, Little Island, Cork, T45 K857, Ireland. **MA Number:** PA 2315/060/002, 003, 004, 005, 006, 007, 008, 009, 010, 011. **Legal Category:** POM. Full prescribing information including the SPC, is available on request from Accord Healthcare Ltd, Euro House, Little Island, Co. Cork, Tel: 021-4619040 or [www.accord-healthcare.ie/products](http://www.accord-healthcare.ie/products). Adverse reactions can be reported to Medical Information at Accord Healthcare Ltd. Via E-mail: [medinfo@accord-healthcare.com](mailto:medinfo@accord-healthcare.com) or Tel: +44(0)1271385257. **Date of Generation of API:** March 2019 UK&IE/MET/0027/06-18(1)

Adverse events should be reported. Reporting forms and information can be found on the HPR website ([www.hpra.ie](http://www.hpra.ie)), or by e-mailing [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Adverse events should also be reported to Medical Information via email: [medinfo@accord-healthcare.com](mailto:medinfo@accord-healthcare.com) or tel: 0044 (0)1271 385257.



(19A111) ABSTRACT 20

REGULAR POSTER 12

**Hypoxia Resistant Pathogenic B cells Accumulate in the RA Synovial Tissue in a CXCR3 Dependent Manner.**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease of unknown and complex aetiology with severe detrimental effects for the patient's quality of life. While autoantibodies have been used extensively for the diagnosis of RA, no clear mechanism of action towards disease pathogenesis and progression has been identified.

**Aims/Background**

Identification of chemokines and their receptors responsible for the accumulation of invading B-cells in the inflamed joint. Characterization of B-cell function under the unique hypoxic conditions of the RA joint.

**Method**

Synovial tissue biopsies from RA patients with paired blood/synovial fluid, were obtained through key-hole arthroscopy followed flow cytometric analysis of B-cell subpopulations and chemokine receptor expression in the periphery and synovial tissue. Multiparametric SPICE analysis for the chemokine receptor expression (CXCR5, CXCR3, CCR7, CCR6, CCR4) of synovial tissue invading B-cells was performed followed by B-cell invasion assays. Functional characterization of RA sorted B-cells, cultured in vitro in a hypoxia chamber simulating the unique environment of the inflamed joint.

**Results**

There is a significant accumulation of CD27<sup>+</sup> and double negative (CD27-IgD<sup>-</sup>) memory B-cells in the synovial tissue and synovial fluid of RA patients irrespective of ACPA status. SPICE analysis of peripheral blood B-cells for a panel of chemokine receptors revealed a definitive bias towards a specific disease dependent chemokine receptor expression pattern, present from arthralgia-early in disease subjects. Tissue invading B-cells showed a clear preference for the expression of CXCR3. Importantly returning RA patient B-cells following rituximab mediated B-cell depletion express high levels of CXCR3. By simulating the unique hypoxic conditions of the inflamed joint, we observed significant alteration in B-cell activation with RA B-cells showing increased pro-inflammatory cytokine production and Glut1 expression. B-cell Glut1 expression correlates with pSTAT3, while blockade of glucose uptake by 2DG abolishes RA B-cell pro-inflammatory cytokine production under normoxic or hypoxic conditions.

**Conclusions**

The accumulation of pro-inflammatory B-cell subpopulations in the synovium of RA patients, is CXCR3 mediated and offers an opportunity for early therapeutic intervention. Once in the hypoxic environment of the inflamed RA joint, B-cells show altered activation, pro-inflammatory cytokine production and metabolism that could prove important for understanding the role of B-cells in disease pathogenesis of RA.

(19A112) ABSTRACT 21

REGULAR POSTER 13

**Increased T Cell Polyreactivity with Marked Accumulation of TNF- $\alpha$  DP (CD4+CD8+) in the Synovial Tissue of pre-RA, Arthralgia Subjects**

**Author(s)**

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**Introduction**

Effective treatment of Rheumatoid arthritis (RA) patients is achievable within a short window of opportunity following diagnosis. Recent studies illustrate the pathogenic effect of increased T cell polyreactivity in autoimmunity, such studies in pre-RA arthralgia subjects have been hindered by the rare availability of synovial biopsy samples and minimal synovial cell recovery. In this study, we describe for the first time, polyreactive T cell responses in the synovial tissue of Arthralgia subjects and RA patients.

**Aims/Background**

Characterization of pro-inflammatory T cell cytokine responses and polyreactivity in the periphery and synovial tissue of pre-RA, Arthralgia subjects and established RA patients.

**Method**

Synovial biopsies of RA patients and arthralgia subjects were obtained by key-hole arthroscopic surgery. Following enzymatic and mechanical digestion of the tissue, a single cell suspension was obtained. Synovial cells and paired PBMC were stimulated in vitro and analysed by 15-colour flow cytometric analysis for the identification of T cell pro-inflammatory cytokine responses. Following multiparametric flow-cytometric analysis, SPICE algorithm and Flowsome unsupervised clustering were utilised to examine peripheral blood and synovial tissue T-cell cytokine polyreactivity of arthralgia subject and RA patients and peripheral blood and synovial fluid Tfh responses.

**Results**

Higher T cell pro-inflammatory cytokine polyreactivity was identified in arthralgia subjects compared to RA patients. Compared to the periphery, synovial tissue T cell polyreactivity is significantly higher with comparable pro-inflammatory cytokine profiles between arthralgia and RA synovial tissue T cells. Flowsome clustering analysis resulted in the identification of novel T cell clusters that exhibit high polyreactivity and an accumulation of DP (CD4+CD8+) in the synovial tissue of arthralgia subjects and RA patients. Peripheral blood Tfh cell frequency is significantly higher in arthralgia subjects compared to RA patients, with an accumulation of germinal centre like-Tfh T cells in the synovial fluid of established RA.

**Conclusions**

Polyreactive pro-inflammatory T cell responses pre-date disease onset as demonstrated by the accumulation of polyreactive T cells in the synovial tissue of pre-RA arthralgia subjects. These data highlight a key early pathogenic role for T cell plasticity and the newly, in autoimmunity, described T cell cluster of DP T cells in RA.



(19A113) ABSTRACT 22

REGULAR POSTER 14

**Group versus individual treatment for rotator cuff tendinopathy: A randomised clinical trial in Primary care.**

**Author(s)**

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**Introduction**

Exercise-based treatment has been shown to be effective for rotator cuff tendinopathy/subacromial impingement syndrome. Research has shown that group-based versus individual physiotherapy results in similar outcomes, in terms of pain & disability, when delivering exercise interventions for musculoskeletal disorders (O'Keeffe et al, 2017).

**Aims/Background**

The primary aim of this trial is to investigate whether group exercise is as effective as multi-modal one-to-one physiotherapy using the Shoulder Pain and Disability Index (SPADI) QuickDASH, the Constant-Murley score (CMS) and the Patient Global Impression of Change (GIC) to assess changes in pain and disability at 6 weeks, 3 months and 6 months.

**Method**

A single-blinded randomised trial was undertaken. 69 patients (49 women, 20 men) with shoulder rotator cuff tendinopathy were recruited from the waiting list of a primary care physiotherapy department, screened for eligibility and provided informed consent to participate in the study. Participants were randomised into the group exercise or usual care arms of the study. Baseline measures (SPADI, QuickDASH and CMS) were administered by an independent assessor blind to the group allocation. These measures plus the GIC were reassessed at 6 weeks, 12 weeks and 6 months. The usual care group received physiotherapy according to their therapist's discretion. The group intervention consisted of 12 sessions (twice weekly for 6 weeks) of a 1 hour circuit-type exercise class.

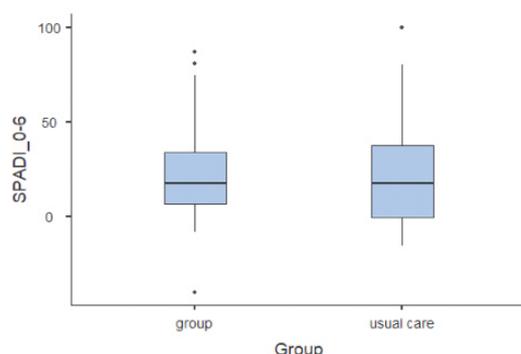
**Results**

69 eligible participants were recruited (35 to group and 34 to individual care), of which 60 completed the trial. Mean duration of shoulder pain was 15.2 months (SD=21.7) and mean age was 64.3 (SD=15.1). Both groups achieved a statistically and clinically significant level of change in SPADI at 6 weeks ( $p < 0.001$  within group) and 6 months follow-up ( $p < 0.001$  within group). There was no statistically significant between-group difference at either time-point ( $p = 0.92$  at 6 weeks,  $p = 0.69$  at 6 months). Similar trends were noted for each of the other outcome measures.

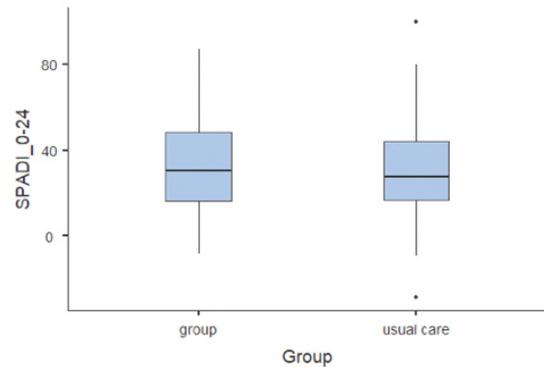
**Conclusions**

There was no difference in outcome for patients with rotator cuff tendinopathy managed either with group or individual physiotherapy. This study supports the use of group-based exercise for management of rotator cuff tendinopathy in a primary care setting as an effective and potentially more resource efficient service.

Figure



Figure



(19A116) ABSTRACT 23

REGULAR POSTER 15

**Incidence and risk factors for developing diabetic foot ulcerations (+risk of Osteomyelitis) in geriatric patients. Relationship between depression, social isolation, and cognitive impairment with DFU**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

Diabetic foot ulceration (DFU) is a well known complication of longstanding poorly controlled diabetes mellitus occurring in 6.3% of people with diabetes. Longstanding suboptimal diabetes control leads to the development of peripheral sensory neuropathy, and requires intensive self care to avoid subsequent ulceration and risk of possible Osteomyelitis.

**Aims/Background**

The hypothesis of this study is that people with depression, cognitive impairment and social isolation self-care less well. The aim of this study is to determine the prevalence of depression, cognitive impairment and social isolation in people with DFU compared to those with peripheral neuropathy but no ulceration

**Method**

This was an observational study conducted in Sligo University Hospital (SUH), Sligo, Ireland. Participants completed a paper based questionnaire including social demographic data, medical history, mini-mental test and depression score. All subjects were assessed by monofilament testing for peripheral neuropathy.

**Results**

52 subjects with peripheral neuropathy were included in the study: 26 with foot ulceration, 26 without ulceration. The study found no significant correlation between DFU and depression, or duration of diabetes. Those with neuropathy but no ulceration were more likely to have a normal hba1c as a marker of good diabetes control. There was significant correlation between male gender and DFU, age of the youngest member in the house, amputation, retinopathy, and degree of neuropathy. There was no significant relationship between DFU and smoking, alcohol, living in a rural area, living alone, type of care, home help, public health nurse visit, attending a day hospital, leaving the house frequency, member of social clubs, driving, diabetic control or PAD.

**Conclusions**

In our study no relationship between depression and DFU was found. This finding is not consistent with the previous studies on similar comparison. Significant relation between DFU and male



gender was noted. Although in our study the duration of disease is not significantly associated with DFU but it was found that normal values of HbA1c were associated with less incidence of DFU.

Figure



(19A117) ABSTRACT 24

REGULAR POSTER 16

### Efficacy and Safety of Filgotinib for Patients with Rheumatoid Arthritis with Inadequate Response to Methotrexate: FINCH 1 Primary Outcome Results

Author(s)

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Introduction

Filgotinib (FIL), an oral, selective Janus kinase 1 inhibitor, has shown efficacy and was well tolerated for rheumatoid arthritis (RA) treatment.

Aims/Background

To evaluate FIL's efficacy and safety in patients with RA and inadequate response to methotrexate (MTX).

Method

This Phase 3, double-blind, active- and placebo (PBO)-controlled study randomised patients with active RA (3:3:2:3) to FIL 200mg, FIL 100mg, adalimumab [ADA] 40mg every 2 weeks or PBO daily up to 52 weeks; results through Week 24 are presented. Patients also received MTX for  $\geq 12$  weeks with stable MTX dose for  $\geq 4$  weeks before study drug initiation. Primary endpoint was proportion achieving ACR20 response at Week 12; additional assessments were ACR50/70, DAS28-CRP  $\leq 3.2$  and 50% of ADA response] was performed for DAS28-CRP  $\leq 3.2$  and  $< 2.6$ .

Results

1,755 patients received the study drug, with 475 FIL 200mg; 480 FIL 100mg; 325 ADA; and 475 PBO. 81.8% were female, mean

(standard deviation [SD]) RA duration 7.8 (7.6) years and mean (SD) DAS28-CRP 5.7 (0.9). At Week 12, significantly more patients on FIL 200mg and 100mg achieved ACR20 response compared with PBO (Table 1). Compared with PBO, more patients receiving FIL achieved ACR50/70 responses, DAS28-CRP  $\leq 3.2$  and  $< 2.6$ , had lower radiographic progression and PROs improvements (Table 1). Non-inferiority of FIL 200mg to ADA was met on DAS28-CRP  $\leq 3.2$ . FIL safety profile was consistent with prior studies through Week 24 (Table 2).

Conclusions

FIL 200mg and 100mg led to significant improvement in signs and symptoms of RA, prevented radiographic progression and improved physical function compared with PBO, and was well tolerated among patients with RA with inadequate response to MTX. Efficacy of FIL 200mg was non-inferior to ADA based on DAS28-CRP  $\leq 3.2$ .

Figure

Table 1. Efficacy at Week 12 (Primary Analysis) and Week 24\*

	FIL 200mg (N=475)		FIL 100mg (N=480)		ADA 40mg Q2W (N=325)		PBO (N=475)	
	Week 12	Week 24	Week 12	Week 24	Week 12	Week 24	Week 12	Week 24
ACR20, %	76.6***	78.1	69.8***	77.7	70.8	74.5	49.9	59.2
ACR50, %	47.2***	57.9	36.3***	52.7	35.1	52.6	19.8	33.3
ACR70, %	26.3***	36.2	18.5***	29.4	14.2	29.5	6.7	14.9
DAS28-CRP $\leq 3.2$ , %	49.7***	60.6	38.8***	53.1	43.4	50.5	23.4	33.7
DAS28-CRP $< 2.6$ , %	33.9***	48.4	23.8***	35.2	23.7	35.7	9.3	16.2
mTSS, mean change from BL	0.08	0.13***	0.11	0.17***	0.13	0.16	0.25	0.38
HAQ-DI, mean change from BL	-0.69***	-0.82	-0.56***	-0.75	-0.61	-0.78	-0.42	-0.62
SF-36 PCS, mean change from BL	9.2***	10.4	8.5***	10.3	8.4	10.4	5.8	7.7
FACIT-Fatigue, mean change from BL	9.2***	10.5	9.1***	10.8	8.8	10.3	6.8	8.4

\* All patients who were randomised and received at least 1 dose of study drug were included in efficacy analyses. P-values are shown only for primary time points (all at Week 12 except mTSS, which was at Week 24).  
\*\*\* P<0.001 vs PBO. \*\* P<0.01 vs ADA non-inferiority test. \* P<0.05 vs ADA non-inferiority test. † P<0.01 vs ADA superiority test.  
\* Comparison not adjusted for multiplicity  
ACR50/70: 20%/50%/70% improvement in American College of Rheumatology criteria; ADA, adalimumab; BL, baseline; DAS28-CRP, Disease Activity Score based in 28 joints with C-reactive protein, FIL, filgotinib; FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire Disability Index; mTSS, modified Total Sharp Score; SF-36 PCS, Short-Form 36 Physical Component Summary; Q2W, every 2 weeks

Figure

Table 2. Safety Events of Interest Through Week 24

Patient with event, n (%)	FIL 200mg (N=475)	FIL 100mg (N=480)	ADA 40mg Q2W (N=325)	PBO (N=475)
	Serious AEs	21 (4.4)	24 (5.0)	14 (4.3)
Serious infections	8 (1.7)	8 (1.7)	8 (2.5)	4 (0.8)
Herpes zoster	2 (0.4)	2 (0.4)	2 (0.6)	2 (0.4)
Adjudicated MACEs	0	1 (0.2)	1 (0.3)	2 (0.4)
Venous thrombotic events	1 (0.2)	0	0	2 (0.4)
Malignancies	0	1 (0.2)	1 (0.3)	3 (0.6)
Deaths	2 (0.4)	1 (0.2)	0	2 (0.4)

AE, adverse event; MACE, major adverse cardiovascular event; Q2W, every 2 weeks

(19A118) ABSTRACT 25

REGULAR POSTER 17

### Efficacy and Safety of Filgotinib for Patients with Rheumatoid Arthritis Naïve to Methotrexate Therapy: FINCH 3 Primary Outcome Results

Author(s)

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Department(s)/Institutions

1. University College Dublin, Dublin, Ireland; 2. University Hospitals Leuven, Leuven, Belgium; 3. Dartmouth College, Lebanon, NH,

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### Summary of the most important points

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(Please refer to the Summary of Product Characteristics before prescribing)

**Metoject** 7.5 mg / 10 mg / 15 mg / 20 mg / 25 mg solution for injection in pre-filled pen.

**Therapeutic indications:** Metoject is indicated for the treatment of Active rheumatoid arthritis in adult patients, severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA and retinoids, and severe psoriatic arthritis in adult patients. **Posology and method of administration:** Metoject should only be prescribed by physicians who are familiar with the various characteristics of the medicinal product and its mode of action. Patients must be educated to use the proper injection technique. The first injection of Metoject PEN should be performed under direct medical supervision. Metoject is injected **once weekly**. The patient must be explicitly informed about the fact that Metoject is administered **once a week only**. It is advisable to determine an appropriate fixed day of the week for the injection. Methotrexate elimination is reduced in patients with a third distribution space (ascites, pleural effusions). Such patients require especially careful monitoring for toxicity, and require dose reduction or, in some cases, discontinuation of methotrexate administration (reference section 5.2 and 4.4 of the SPC). **Adults, rheumatoid arthritis:** The recommended initial dose is 7.5 mg of Metoject once weekly, administered subcutaneously. Depending on the individual activity of the disease and tolerability, the dose may be increased gradually by 2.5 mg per week. A weekly dose of 25 mg should in general not be exceeded. Upon achieving the therapeutically desired result, the dose should be reduced gradually to the lowest possible effective maintenance dose. Use in children < 3 years of age is not recommended as insufficient data on efficacy and safety is available for this population (reference section 4.4 of the SPC). **Dosage in patients with psoriasis vulgaris, psoriatic arthritis:** It is recommended that a test dose of 5 – 10 mg should be administered parenterally one week prior to therapy to detect idiosyncratic adverse reactions. The recommended initial dose is 7.5 mg of methotrexate once weekly, administered subcutaneously. The dose is to be increased gradually, but should not, in general, exceed a weekly dose of 25 mg of methotrexate. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. Upon achieving the therapeutically desired result, the dose should be reduced gradually to the lowest possible effective maintenance dose. Maximum weekly dose. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. In a few exceptional cases a higher dose might be clinically justified, but should not exceed a maximum weekly dose of 30 mg of methotrexate as toxicity will markedly increase. Patients with renal impairment: Metoject should be used with caution in patients with impaired renal function (see section 4.3 of SPC for further information). Patients with hepatic impairment: Methotrexate should be administered with great caution, if at all, to patients with significant current or previous liver disease, especially if due to alcohol. If bilirubin is > 5 mg/dl (85.5 µmol/l), methotrexate is contraindicated. **Elderly:** Dose reduction should be considered due to reduced liver and kidney function as well as lower folate reserves. Use in patient with a third distribution space (pleural effusions, ascites): As the half-life of methotrexate can be prolonged to 4 times the normal length in patients who possess a third distribution space dose reduction or, in some cases, discontinuation of methotrexate administration may be required (see section 5.2 and 4.4 of the SPC). Instructions for subcutaneous use: If changing the oral application to parenteral administration a reduction of the dose may be required due to the variable bioavailability of methotrexate after oral administration. **Contraindications:** Hypersensitivity to methotrexate or any of the excipients (reference section 6.1 of the SPC); severe liver impairment (reference section 4.2 of the SPC); alcohol abuse; severe renal impairment (creatinine clearance < 30 ml/min reference section 4.2 and section 4.4 of the SPC); pre-existing blood dyscrasias (bone marrow hypoplasia, Leukopenia, thrombocytopenia, significant anaemia); serious, acute or chronic infections such as tuberculosis, HIV, other immunodeficiency syndromes; ulcers of the oral cavity and known active gastrointestinal ulcer disease; pregnancy, breast-feeding (reference section 4.6 of the SPC); concurrent vaccination with live vaccines.

**Special warnings and precautions for use:** Patients must be clearly informed that the therapy has to be administered **once a week**, not every day. Patients undergoing therapy should be subject to appropriate supervision so that signs of possible toxic effects or adverse reactions may be detected and evaluated with minimal delay. Therefore treatment with methotrexate should only be initiated and supervised by physicians whose knowledge and experience includes the use of antimetabolite therapy. Because of the possibility of severe or even fatal toxic reactions, the patient should be fully informed by the physician of the risks involved and the recommended safety measures. Recommended examinations and safety measures: Before beginning or reinstating methotrexate therapy after a rest period: Complete blood count with differential blood count and platelets; liver enzymes; bilirubin; serum albumin, chest x-ray and renal function tests. If clinically indicated, exclude tuberculosis and hepatitis, see section 4.4 of the SPC for further information). During therapy (at least once a month during the first six months and every three months thereafter): An increased monitoring frequency should be considered also when the dose is increased, see section 4.4 of the SPC for further information).

**Sodium:** This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free". **Interactions with other medicines:** Special care should be taken with Methotrexate and Alcohol, hepatotoxic medicinal products, haematotoxic medicinal products, oral antibiotics, antibiotics, medicinal products with high plasma protein binding, probenecid, weak organic acids, pyrazoles, non-steroidal anti-inflammatory agents, medicinal products with adverse reactions on the bone marrow, medicinal products which cause folate deficiency, folic acid, other antirheumatic medicinal products, subhasazine, mercaptopurine, proton-pump inhibitors, theophylline, caffeine or theophylline-containing beverages. **Fertility, pregnancy and lactation:** Methotrexate is contraindicated during pregnancy and is excreted in breast milk and there is a risk for the infant. Methotrexate can be genotoxic. All women are advised to consult a genetic counselling centre, if possible, already prior to therapy. Men should seek advice about the possibility of sperm preservation before starting therapy. **Effects on ability to drive and use machines:** Central nervous symptoms such as tiredness and dizziness can occur during treatment. Metoject has minor or moderate influence on the ability to drive and use machines. **Undesirable effects:** The following headings are used to organise the undesirable effects in order of frequency: Very common (≥ 1/100 to < 1/10), common (≥ 1/1,000 to < 1/100), rare (< 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data). The most relevant undesirable effects are suppression of the haematopoietic system and gastrointestinal disorders. **Very common:** Gastrointestinal disorders (Stomatitis, dyspepsia, nausea, loss of appetite, abdominal pain) and Hepatobiliary disorders (Abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin)). **Common:** Blood and lymphatic system disorders (Leukopenia, anaemia, thrombopenia), **Uncommon:** Infections and infestations (Pharyngitis), Blood and lymphatic system disorders (Pancytopenia), Metabolism and nutrition disorders (Precipitation of diabetes mellitus), Psychiatric disorders (Depression, Confusion), Nervous System Disorders (dizziness) and Gastrointestinal disorders (Gastrointestinal ulcers and bleeding, enteritis, vomiting, pancreatitis). **Hepatobiliary disorders:** Cirrhosis, fibrosis and fatty degeneration of the liver, decrease in serum albumin). Skin and subcutaneous tissue disorders (Photosensitisation, loss of hair, increase in melanotic nodules, skin ulcer, herpes zoster, vasculitis, herpetiform eruptions of the skin, urticaria). Musculoskeletal and connective tissue disorders (Arthralgia, myalgia, osteoporosis). Renal and urinary disorders (Inflammation and ulceration of the urinary bladder, renal impairment, disturbed micturition) and Reproductive system and breast disorders (Inflammation and ulceration of the vagina). **Rare:** Infections and infestations (Infection (incl. reactivation of inactive chronic infection), sepsis, Pneumocystis jirovecii pneumonia, conjunctivitis). Immune system disorders (Allergic reactions, anaphylactic shock, hypogammaglobulinaemia). Psychiatric disorders (Mood alterations). Eye disorders (visual disturbances). Cardiac disorders (Pericarditis, pericardial effusion, pericardial tamponade), VASCULAR DISORDERS (Hypotension, thromboembolic events). Respiratory, thoracic and mediastinal disorders (Pulmonary fibrosis, shortness of breath and bronchial asthma, pleural effusion). Gastrointestinal disorders (Gingivitis). Hepatobiliary disorders (acute hepatitis). Skin and subcutaneous tissue disorders (Increased pigmentation, acne, petechiae, ecchymosis, allergic vasculitis), Musculoskeletal and connective tissue disorders (stress fracture). Renal and urinary disorders (Renal failure, oliguria, anuria, electrolyte disturbances). General disorders and administration site conditions (Fever, wound-healing impairment). See Section 4.8 of the SPC for very rare and unknown undesirable effects.

**Overdose:** Calcium folinate is the specific antidote for neutralising the toxic undesirable effects of methotrexate.

**Legal classification:** POM. Marketing authorisation holder: Medac Gesellschaft für Klinische Spezialpräparate mbH Theaterstrasse 6, 22880 Wedel, Germany. Marketing authorisation number: PA0623/014/002, PA0623/014/003, PA0623/014/004, PA0623/014/005, PA0623/014/006 Date of revision of text: June 2018.

For a copy of the SmPC or further medical information, please contact [medica@dcvital.com](mailto:medica@dcvital.com).

Adverse events should be reported to Fannin Ltd, Pharmacovigilance at +353 (0)86 839 4447 or [medica@dcvital.com](mailto:medica@dcvital.com).

**Reporting of suspected adverse reactions:** Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via HPA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 (0) 1 676 4971; Fax: +353 (0) 1 676 2517; Website: [www.hpra.ie](http://www.hpra.ie); Email: [medsafely@hpra.ie](mailto:medsafely@hpra.ie).

**Additional information available on request.**

**References:** 1. Hatteson J et al, German Society Rheumatology 2017 doi: 10.3205/17dgm244.



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USA; 4. Leiden University Medical Center, Leiden, Netherlands; 5. Timaru Hospital, Timaru, New Zealand; 6. Gilead Sciences, Inc., Foster City, CA, USA; 7. Galapagos NV, Mechelen, Belgium; 8. Cosme Argerich Hospital and IRO Medical Center, Buenos Aires, Argentina; 9. Amsterdam University Medical Center, Amsterdam, Netherlands; 10. Hokkaido University, Sapporo, Japan; 11. Charité – University Medicine Berlin, Berlin, Germany

**Introduction**

Filgotinib (FIL), an oral selective Janus kinase 1 inhibitor, has shown efficacy and was well tolerated for rheumatoid arthritis (RA) treatment.

**Aims/Background**

To compare efficacy and safety of FIL with and without methotrexate (MTX) in patients with RA naïve to MTX.

**Method**

This Phase 3, double-blind, active-controlled study randomised patients with moderately to severely active RA (2:1:1:2) to FIL 200mg daily + MTX weekly (up to 20mg), FIL 100mg + MTX, FIL 200mg (+placebo [PBO]), or MTX (+PBO) up to 52 weeks; results are through Week 24. Primary endpoint was proportion achieving ACR20 response at Week 24; additional assessments included ACR50/70 responses; DAS28-CRP  $\leq 3.2$  and  $< 2.6$ , and changes in van der Heijde mTSS, and patient-reported outcomes (PROs). Safety endpoints included adverse event types and rates. Logistic regression adjusting for stratification factors with non-responder imputation was used for treatment comparisons for binary endpoints. Mixed-effect model adjusting for baseline value, stratification factors, treatment, visit and treatment by visit interaction was used for continuous endpoints.

**Results**

1,249 patients received the study drug (416 FIL 200mg+MTX; 207 FIL 100mg+MTX; 210 FIL 200mg monotherapy; 416 MTX monotherapy). 76.9% were female; mean time since RA diagnosis 2.2 years (median 0.4 years); mean (standard deviation) DAS28-CRP 5.7 (1.0); and 35.9% using oral steroids at baseline. At Week 24, significantly more patients on FIL 200mg + MTX (81.0%;  $P < 0.001$ ) and FIL 100mg + MTX (80.2%;  $P < 0.05$ ) achieved ACR20 response compared with MTX monotherapy (71.4%; Table 1). Compared with MTX monotherapy, more patients receiving FIL with or without MTX achieved ACR50 and ACR70, DAS28-CRP  $< 2.6$  and  $\leq 3.2$  and SF-36 PCS improvements (Table 1). Onset of activity was rapid, with significantly more achieving ACR50 and DAS28-CRP  $< 2.6$  with FIL than MTX at Week 2. FIL safety was consistent with prior studies through Week 24 (Table 2).

**Conclusions**

FIL + MTX had significant improvements in RA signs and symptoms, physical function and PROs compared to MTX alone and was well tolerated in patients with early active RA naïve to MTX. Clinically meaningful response to FIL occurred as early as 2 weeks after treatment initiation.

Figure

Table 1. Efficacy Outcomes at Week 24\*

	FIL 200 mg + MTX (N=416)	FIL 100 mg + MTX (N=207)	FIL 200mg Monotherapy (N=210)	MTX Monotherapy (N=416)
ACR20, %	81.0***	80.2*	78.1	71.4
ACR50, %	61.5***	57.0**	58.1***	45.7
ACR70, %	43.8***	40.1***	40.0***	26.0
DAS28-CRP $\leq 3.2$ , %	68.8***	62.8***	60.0***	46.2
DAS28-CRP $< 2.6$ , %	54.1***	42.5***	42.4***	29.1
mTSS, mean change from BL	0.20	0.22	-0.04***	0.52
HAQ-DI, mean change from BL	-0.94***	-0.90**	-0.89**	-0.79
SF-36 PCS, mean change from BL	12.3***	11.1**	10.4	9.7
FACIT-Fatigue, mean change from BL	10.6	11.4	10.2	10.1

\* All patients who were randomised and received at least 1 dose of study drug were included in efficacy analyses; \*\*  $P < 0.05$  vs MTX monotherapy; \*\*\*  $P < 0.01$  vs MTX monotherapy; \*\*\*\*  $P < 0.001$  vs MTX monotherapy; \* Comparison not adjusted for multiplicity  
ACR20/50/70: 20%/50%/70% improvement in American College of Rheumatology criteria; BL: baseline; DAS28-CRP: Disease Activity Score based in 28 joints with C-reactive protein; FACIT: Functional Assessment of Chronic Illness Therapy; F: Fatigue; HAQ-DI: Health Assessment Questionnaire Disability Index; mTSS: modified total Sharp score; MTX, methotrexate; PBO, placebo; SF-36 PCS: Short-Form 36 Physical Component Summary

Figure

Table 2. Safety Events of Interest Through Week 24

Patients with event, n (%)	FIL			
	FIL 200 mg + MTX (N=416)	FIL 100 mg + MTX (N=207)	200mg Monotherapy (N=210)	MTX Monotherapy (N=416)
Serious AEs	17 (4.1)	5 (2.4)	10 (4.8)	12 (2.9)
Serious infections	4 (1.0)	2 (1.0)	3 (1.4)	4 (1.0)
Herpes zoster	2 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Adjudicated MACEs	2 (0.5)	0	1 (0.5)	2 (0.5)
Venous thrombotic events	0	0	0	1 (0.2)
Malignancies	0	0	0	1 (0.2)
Deaths	1 (0.2) <sup>a</sup>	0	0	0

<sup>a</sup> Cause of death was lupus myocardioopathy  
AE: adverse event; MACE: major adverse cardiovascular event

(19A125) ABSTRACT 26

REGULAR POSTER 18

**Audit on osteoporosis assessment and management in patients with chronic obstructive pulmonary disease (COPD)**

**Author(s)**

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**Department(s)/Institutions**

Department of respiratory medicine, Sligo University Hospital, Saolta University Health Care Group

**Introduction**

COPD is a chronic airway inflammatory disease associated with multiple co-morbidities including osteoporosis. Osteoporotic fractures have dramatic impacts on quality of life and even respiratory function in patients with COPD.

COPD associated osteoporosis is however hugely under-recognised and under treated.

Various risk factors of osteoporosis in COPD patients, including older age, low body mass index, physical inactivity, smoking, corticosteroid use and vitamin D deficiency have been described.

**Aims/Background**

We aimed to determine whether patients attending the respiratory department with a diagnosis of COPD were screened for osteoporosis and getting the appropriate treatment.

**Method**

32 patients attending the respiratory outpatient department with a diagnosis of COPD were included.

We evaluated the following: their bone mineral density (BMD) using bone densitometry scan (DEXA) in the past 3 years, their 10-year probability of bone fracture risk was calculated using the Fracture Risk Assessment Tool (FRAX), the use of anti-osteoporotic treatment for these patients.

**Results**

26/32 patients were over 65 years old and 15 of these were on adequate anti-osteoporotic treatment.

Out of 11 patients with previous fractures; 3 were not recorded to being prescribed for bone protection and 3 did not have a DEXA scan within the previous 3 years.

Out of the 6 patients with a diagnosis of osteoporosis based on their BMD; 5 were adequately prescribed with bone protection.

The commonest site for fracture was vertebral (6/11); other fracture sites included wrist, pubic ramus, humerus, rib, and finger.

**Conclusions**

Recent studies would advise that any symptomatic COPD patient over the age of 50 years old should be screened for potential indication of pharmacological treatment.

FRAX underestimates the COPD-associated fracture risk and additional risk factors such as reduced physical activity; severely

# When life is too busy for RA

Given a choice, 53% of RA patients would chose a monthly regime<sup>1\*</sup>



## GO further with Simponi

With Simponi, approximately 70% of patients remained on treatment after 5 years.<sup>2</sup> Make your 1st choice count.



### SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)

**ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre filled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **INDICATIONS** *Rheumatoid Arthritis (RA)*: Simponi, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA)*: Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS)*: Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA)*: Simponi is indicated for the treatment of severe, active nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. *Ulcerative colitis (UC)*: Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Polyarticular juvenile idiopathic arthritis (pJIA)*: Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **DOSE AND ADMINISTRATION** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA, UC or pJIA. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. **RA**: Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. **PsA**: Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. **AS and nr-Axial SpA**: Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. **UC**: *Patients weighing < 80 kg*: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2. Patients who have an adequate response should receive 50 mg at week 6 and every 4 weeks thereafter. Patients who have an inadequate response may benefit from continuing with 100 mg at week 6 and every 4 weeks thereafter. *Patients weighing ≥ 80 kg*: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). **pJIA**: Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3-4 doses). **Missed dose**: If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. **Elderly patients (> 65 years)**: no dose adjustment required. **Paediatric patients (<18 years)**: For indications other than pJIA, Simponi is not recommended. **Patients with renal and hepatic impairment**: Simponi is not recommended. **CONTRAINDICATIONS** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS AND WARNINGS** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Reminder Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. **Hepatitis B (HBV) reactivation**: Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi. **Malignancies and lymphoproliferative disorders**: Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6 mercaptopurine (6-MP). The potential risk with the combination of AZA or 6 MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma and Merkel cell carcinoma (all TNF-blocking agents including Simponi) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer.

**Heart Failure**: Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. **Neurological events**: Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery**: Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes**: If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions**: There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers, including Simponi. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents**: It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions**: If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations**: **Elderly patients (> 65 years)**: Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. **Paediatric patients (<18 years)**: **Vaccinations**: it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. **Excipients**: Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **INTERACTIONS** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **PREGNANCY AND LACTATION** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **SIDE EFFECTS Refer to SmPC for complete information on side effects** **Very Common (≥ 1/10)**: upper respiratory tract infection; **Common (≥ 1/100)**: bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, Leukopenia (including neutropenia), anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, hepatosplenic T-cell lymphoma\*, leukopenia, thrombocytopenia, pancytopenia, aplastic anaemia, agranulocytosis, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. \*Observed with other TNF-blocking agents. **Paediatric population**: pJIA: The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection **Legal Category**: Prescription Only Medicine. **Marketing Authorisation Number** 50 mg Pre-filled Pen EU/1/09/546/001 50 mg Pre-filled Syringe EU/1/09/546/003 100 mg Pre-filled Pen EU/1/09/546/005 **Marketing Authorisation Holder** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands **Date of Revision of Text**: September 2018 **Simponi**/PI-IRE/09-18 © Merck Sharp & Dohme Ireland (Human Health) Limited 2018. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to MSD (Tel: 01-2998700) **Date of preparation**: March 2019

Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie).  
Adverse events should also be reported to MSD (Tel: 01-2998700)

**References**: 1. Huynh, T.K. et al. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. Patient Preference and Adherence, 2014; 8: 93-99. 2. Keystone EC, Genovese MC, Hall S et al. Safety and efficacy of subcutaneous golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: final 5-year results of the GO-FORWARD trial. J Rheumatol. 2016;43:298-306. \*Rheumatoid arthritis patients preferring subcutaneous therapies



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impaired lung function and height loss should be included in risk stratification.

Patients at potential risk should then be examined for BMD by DXA. Prevalent vertebral fractures and systemic corticosteroid therapy are a strong indication of medical treatment.

Until a specific treatment guideline for COPD-associated osteoporosis is proposed, individuals with COPD should be screened, early diagnosis should be made and treatment measures put in place to prevent future fracture risk.

Figure

<b>Total number of patients</b>	<b>32</b> Female 59.4%, Male 40.6%
<b>Age (Mean)</b>	73 (Range 48-89)
<b>Patients with previous fractures</b>	11/32 (34.4%)
<b>DEXA within past 3 years</b>	15/32 (46.9%)
<b>Anti-osteoporotic treatment prescribed</b>	15/32 (46.9%)
<b>FRAX- 10-year probability of major osteoporotic Fracture (Mean)</b>	16.1% (Range 3.4%-36%)
<b>FRAX- 10-year probability of hip fracture</b>	7.6% (Range 0.3%- 23%)

(19A127) ABSTRACT 27

REGULAR POSTER 19

## A Quality Improvement Intervention to Increase Pneumococcal and Influenza Vaccination Amongst Immunosuppressed Inflammatory Arthritis Patients

Author(s)

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Department(s)/Institutions

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Introduction

CDC guidelines recommend influenza and 23-valent pneumococcal polysaccharide (PPSV23) vaccination for inflammatory arthritis (IA) patients on immunosuppression.

Aims/Background

This study aimed to:

- 1). assess barriers to vaccination
- 2). increase PPSV23 (5 yearly) and "flu" (annual) vaccination uptake in immunosuppressed IA outpatients through a multifaceted quality improvement (QI) intervention. The primary outcome was adequate PPSV23 and "flu" vaccination of immunosuppressed IA outpatients.

Method

Consecutive outpatients from 2017 were invited to complete an anonymous 23 question paper questionnaire including demographic, diagnostic, medication and vaccination (knowledge, status and barriers) data. Patients taking oral steroids, biologic DMARDs (bDMARDs) or immunosuppressant conventional synthetic agents (csDMARDs) were included.

Simultaneously, a low cost multifaceted QI intervention was performed. This involved staff education sessions, patient information questionnaires, point-of-care paper "Arthritis and Infection Worksheets" and "Vaccination Advice Letters" highlighting outstanding vaccinations to the patient's GP. In 2018, post-intervention, the clinic was re-assessed. Binary logistic regression analysis was used to assess for independent predictors of up-to-date vaccination.

Results

In 2017-2018, 163 and 262 patients, respectively, met inclusion criteria. Patients were typical of an IA clinic (74% women; 45.4% ≥60 years old; 72.7% RA; 61.1% using csDMARDs; 46.6% using bDMARDs; 23.1% using combination csDMARD plus bDMARD; 32.5% using oral steroids).

In 2017, 104 (65.4%) knew of the increased infectious risk with IA. In 2018, 168 (65.6%) were aware. In 2017, 111 (69.8%) were aware of increased infection risk with medications; 172 (66.9%) in 2018.

Vaccination rates and awareness were higher for "flu" (Table 1). GPs informed and vaccinated most patients. The most common reason for non-vaccination was lack of awareness. 70% of patients had smart phone access. 78% were willing to use this for vaccination reminders. Age, bDMARD use and up-to-date influenza vaccination were significant predictors of PPSV23 vaccination (Table 2). Only, up-to-date PPSV23 vaccination predicted "flu" vaccination.

Conclusions

Influenza and PPSV23 vaccination rates were suboptimal and increased marginally. One potential solution is point-of-care vaccination in clinic. We have applied for funding for this. Currently, <5% of vaccinations are in hospital. Specialists sharing responsibility with GPs may optimise vaccination timing, safety and uptake.

Figure

Table 1. Vaccination rates, awareness, provision and reasons for non-compliance

	Influenza		PPSV23	
	2017	2018	2017	2018
<b>Adequate vaccination</b>	89 (61.8%)	146 (62.1%)	48 (41%)	92 (47.2%)
	(p=0.29, Pearson Chi squared)		(p=0.95, Pearson Chi squared)	
<b>Vaccination awareness</b>	128 (80%)	212 (81.9%)	60 (38%)	118 (46.8%)
<b>Aware of frequency</b>	133 (99.3%)	219 (99.1%)	59 (75.6%)	98 (65.8%)
<b>Source of awareness</b>				
GP	92 (73%)	146(71.2%)	49 (75.4%)	87 (70.2%)
Hospital	29 (23%)	44 (21.5%)	15 (23.1%)	27 (21.8%)
Clinical Nurse Specialist	0	12 (5.9%)	0	8 (6.5%)
Public Health/Ward Nurse	0	8 (3.9%)	0	1 (0.8%)
Radio	6 (4.8%)	9 (4.4%)	1 (1.5%)	1 (0.8%)
Television	5 (4%)	6 (2.9%)	0	0
Internet/Social Media	1 (0.8%)	3 (1.5%)	0	0
<b>Site of last vaccine</b>				
GP	93 (78.8%)	149(77.2%)	53(89.8%)	98 (90.7%)
Work	7 (5.9%)	14 (7.3%)	0	0
Pharmacy	6 (5.1%)	3 (6.7%)	0	1 (0.9%)
Public Health Nurse	6 (5.1%)	10 (5.2%)	1 (1.7%)	3 (2.8%)
Hospital	4 (3.4%)	5 (2.6%)	3 (5.1%)	4 (3.7%)
Other	2 (1.7%)	2 (1.0%)	2 (3.4%)	3 (2.8%)
<b>Reason not vaccinated</b>				
Unaware	18 (36.7%)	26 (34.2%)	69 (82.1%)	94 (76.4%)
Fear of side effects	12 (24.5%)	18 (23.7%)	7 (8.3%)	10 (8.1%)
Too busy	6 (12.2%)	10 (13.2%)	0	1 (0.8%)
Cost	2 (4.1%)	2 (2.6%)	0	1 (0.8%)
Other	13 (26.5%)	22 (28.9%)	8(9.5%)	17 (13.8%)

Figure

Table 2. Predictors of adequate vaccination

	Influenza		PPSV23	
	OR (95% CI)	p value	OR (95% CI)	p value
<b>Female</b>	0.54 (0.26-1.13)	0.100	1.73 (0.84-3.56)	0.139
<b>Age, years (vs ≤39)</b>				
40-59	0.89 (0.33-2.43)	0.821	7.26 (1.93-27.23)	0.003
60-79	1.11 (0.37-3.30)	0.855	10.33 (2.61-40.86)	0.001
≥80	1.18 (0.08-15.64)	0.903	41.66 (3.69-469.8)	0.003
<b>Education level (vs university)</b>				
Primary	2.82 (0.86-9.30)	0.088	0.70 (0.24-2.06)	0.511
Secondary	1.05 (0.50-2.20)	0.897	0.97 (0.45-2.09)	0.933
<b>Diagnosis (vs RA)</b>				
Psoriatic arthritis	0.36 (0.13-1.00)	0.050	2.50 (0.88-7.07)	0.084
Ankylosing spondylitis	0.68 (0.12-3.89)	0.661	0.28 (0.02-3.66)	0.335
<b>Medications</b>				
bDMARD (vs not)	0.99 (0.45-2.21)	0.987	2.80 (1.24-6.32)	0.013
csDMARD & bDMARD (vs not)	1.49 (0.61-3.67)	0.386	0.71 (0.30-1.70)	0.444
<b>PPSV23 up to date</b>	8.93 (4.39-18.17)	0.000		
<b>Influenza up to date</b>			9.01 (4.40-18.42)	0.000
<b>Smart phone</b>				
Access	1.03 (0.38-2.77)	0.952	0.74 (0.28-1.99)	0.555
Willing to use for reminders	1.45 (0.56-3.80)	0.445	0.64 (0.23-1.77)	0.392

OR=Odds ratio



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REGULAR POSTER 20

**Use of biologics in older patients with inflammatory arthritis**

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**Introduction**

Biologics are a key component of the treatment armamentarium for inflammatory arthritis. Older patients are often omitted from clinical trials in favour of younger subjects. As a result, gaps in the knowledge remain surrounding the prescription, efficacy and safety of biologics in this older population.

**Aims/Background**

The aim of this study is to describe the use of biologics amongst older patients with inflammatory arthritis and compare it to younger patients.

**Method**

This was a retrospective cohort study of patients with a diagnosis of inflammatory arthritis who were receiving a biologic. Data was collected from medical charts at rheumatology outpatient clinics. Patients were divided into two groups based on age: younger group (age 45 – 65) and older group (age >70).

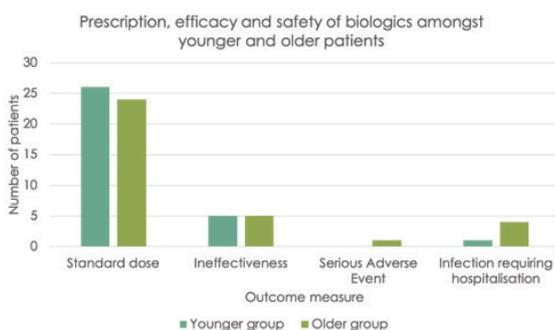
**Results**

Each group had 30 patients (total n=60). 58% were female and the mean age overall was 65 years. There were 4 diagnoses, rheumatoid arthritis being the most common (57%). 8 patients had active disease, and these were mainly older patients (n=6). 8 different biologics featured; the majority of patients received the standard dose of biologic (87% of younger, 80% of older). The incidence of biologic discontinuation due to drug ineffectiveness was the same for both groups (16%). 1 older patient had a biologic discontinued due to a serious adverse event. Infections requiring hospitalisation were not common (total n=5) but were more frequent amongst older patients (n=4). 47% of younger and 60% of older patients received concomitant therapy; most received a disease-modifying anti-rheumatic drug (DMARD) (72%), and those who received a steroid (n=6) were more likely to be older (n=5).

**Conclusions**

Biologic prescribing was similar between both groups with regard to the dosage administered, but there were differences in the types of biologics prescribed to each group. Rates of significant infection were low overall, however they were more prevalent amongst the older population. More older patients had active disease, and more were prescribed concomitant steroid therapy, which may represent under-dosing of biologic therapy in this older cohort.

Figure



(19A130) ABSTRACT 29

REGULAR POSTER 21

**National Fibromyalgia Audit 2019**

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**Introduction**

Fibromyalgia is a common condition with an estimated prevalence of 2% of the general population. The prevalence of fibromyalgia is further increased in patients with chronic inflammatory arthritis and systemic autoimmune rheumatic diseases. However diagnosis and management of this condition remain a challenge.

**Aims/Background**

This audit set out to evaluate the current diagnostic methods, patient education techniques, therapeutic interventions and follow up given to patients with fibromyalgia all over the Republic of Ireland. We also aimed to assess any unmet needs in the provision of care.

**Method**

A questionnaire was issued to all permanent public Rheumatology Consultants practising in the Republic of Ireland. 37 were identified and 29 responded to our request. Questions were formulated to assess compliance with the EULAR 2016 working group recommendations for fibromyalgia care and also to identify areas where these recommendations are unable to be implemented due to lack of resources. Consultants were also specifically asked to specify areas they deemed in need of provision in order to attain recommended interventions.

**Results**

31% (9) of consultants diagnose fibromyalgia with the 1990 criteria while 38% (11) diagnose fibromyalgia with the ACR 2010 criteria and 31% (9) use alternative means for diagnosis. 10.3% (3) use the Fibromyalgia Impact Questionnaire to measure physical functioning, work status, depression, anxiety, morning tiredness, pain, stiffness, fatigue, and well-being at diagnosis. 89.7% (26) do not routinely use this measurement at diagnosis. 13.8% (4) of consultants use the Functional Pain Scale at diagnosis, while 86.2% (25) do not. A minority, 27.6% (8) of respondents document a pain score at diagnosis while 72.4% (21) do not. 51.7% (15) of consultants issue patients with a written information sheet at diagnosis while 48.3% (14) do not do this routinely. 17.2% (5) of patients are referred for consultation with the Specialist Rheumatology Nurse on diagnosis while 82.8% (24) are not. 24.1% (7) of patients are referred to an internet education tool, with the most common responses being either the Arthritis Ireland online resources or Fibro-Ireland resources. 75.9% (22) are not recommended online resources.

44.8% (13) of patients are offered education classes run by their diagnosing rheumatology department, while 55.2% (16) do not have access to department run education classes. Of the 44.8% of patients who have access to educational classes 38.5% (5) are a full day class, 46.2% (6) are half day classes and 15.9% (2) did not indicate if the classes were a full-day or half-day programme. Classes are run by a variety of health care professionals. 30.8% (4) are run by physiotherapist, 30.8% (4) are run by physiotherapist and occupational therapist, 30.8% (4) are run by specialist nurse, physiotherapist and occupational therapist and 7.6% (1) are run by physiotherapist and psychologist. 13.8% (4) of rheumatology departments run specific exercise classes as is one of the recommendations of the EULAR 2016 working group, while 86.2% (25) do not.

In terms of treatment, 55.2% (16) of consultant rheumatologists report that they base their treatment on the EULAR 2016 guidelines, while 44.8% (13) do not. 51.7% (15) start simple analgesia at diagnosis, 34.5% (10) do not routinely and 13.8% (4) did not answer this question. 65.5% (19) consultants start some form of pharmacotherapy



at diagnosis, while 10.3% (3) commence pharmacotherapy after education and 6.9% (2) start pharmacotherapy at both diagnosis and after education depending on the clinical circumstances. 17.2% (5) did not answer this question. 68.9% (20) respondents limit pharmacotherapy to amitriptyline/duloxetine/pregabalin/tramadol as per EULAR 2016 guidelines. 20.9% (6) don't strictly adhere to these guidelines and 10.3% (3) did not indicate a response. When asked if opiates other than tramadol are routinely prescribed 10.3% (3) prescribe other opiates while 89.7% (26) do not.

79.3% (23) recommend mindfulness classes to their patients while 20.7% (6) do not. 96.6% (28) recommend aerobic and strengthening programmes to their patients as diagnosis, while 3.4% (1) do not. Regarding acupuncture, 31% (9) recommend acupuncture to their patients, 65.5% (19) do not recommend acupuncture routinely and 3.5% (1) did not respond to this question.

96.6% of consultants recommend aerobic and strengthening exercise to their patients while 3.4% do not. 69% (20) recommend hydrotherapy to their patients while 31% (9) do not. 41.4% (12) consultants have access to hydrotherapy for their patients. This access is available in the greater Dublin area, North West and Cork and Limerick, while 58.6% (17) do not have access to this resource. 24.1% (7) of consultants admit patients for multidisciplinary assessment, while 75.9% do not routinely. Of those who do not routinely admit their patients, 10.3% (3) indicated it was due to lack of access, 58.6% (17) felt it was not necessary and 31.1% (9) did not reply to this question. Admission for MDT assessment occurs in the greater Dublin area, West and North-West.

41.4% (12) of consultants have had patients discuss use of cannabis with them, 37.9% (11) have not had this discussion and 20.7% (6) did not respond to this question. 17.2% (5) of consultants use trigger point injections for pain relief while 82.8% do not routinely.

55.2% (16) of consultants refer their patients for cognitive behavioural therapy (CBT), one of the 100% consensus recommendations by the EULAR 2016 Fibromyalgia working group. Only 6.9% (2) consultants have direct access to CBT, with 93.1% with no direct access. One hospital in the South East was the only site with direct access. Only 6.9% of consultants have access to CBT via primary care, with 86.2% (25) with no access, even via primary care and 6.9% (2) unsure about access. There was 100% lack of direct access to counselling services nationwide. No respondents were aware of the Counselling in Primary Care (CIPC) programme where they can access counselling services via the primary care practitioner.

#### Conclusions

This audit shows there is varied clinical practice in treating patients with fibromyalgia with regard diagnostic criteria, pharmacotherapy, education, MDT input and follow up. There is geographical variance in access to admission for MDT assessment, with this only available in the greater Dublin area, West and North-West. Hydrotherapy also lacks nationwide availability, currently available Cork, Leitrim and Dublin. Only one centre in the South East has direct access to cognitive behavioural therapy (CBT) sessions delivered by a Psychotherapist. Supportive measures in the form of counselling may be offered for chronic disease management as the next best alternative to CBT. However there was widespread lack of awareness of the Counselling in Primary Care (CIPC) programme, offered via primary care referral and available to medical card patients.

(19A133) ABSTRACT 30

REGULAR POSTER 22

### Patients with Hand Osteoarthritis have a long duration of symptoms and significant pain scores at the time of referral to Rheumatology services.

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#### Introduction

Osteoarthritis is the most common arthritic condition worldwide affecting 9.6% of men and 18% of women aged >60 years<sup>1</sup> with an Irish prevalence >50 years of age is 17.3% for women and 9.4% for men<sup>2</sup>.

It can occur in any joint but is most common in the hip, knee and spine<sup>1</sup>. It is also prevalent in the hand and can lead to significant pain and disability.

#### Aims/Background

To examine the pattern and severity of hand osteoarthritis in patients referred to a regional rheumatology service.

#### Method

Consecutive patients seen in General Rheumatology clinics of all ages and gender who had confirmed diagnosis of hand osteoarthritis based on the ACR criteria were recruited (Patients with RA, Psoriatic Arthritis, Gout, Haemochromatosis were excluded). All gave written informed consent to participate and had a single assessment performed including demographic details, symptom assessment using the AUSCAN Osteoarthritis Hand Index<sup>3</sup>. In addition measures of functional ability, grip strength and pincer strength were performed in the OT department. All patients also had an up to date hand X-Ray performed. For the purposes of this paper we will report the initial assessments including the demographic details and pain scores.

#### Results

100 consecutive unselected patients were included in this analysis. M:F ratio 1:5.25. Mean age was 66.13 years. Mean duration of symptoms 74.63 months(8-422). At assessment the mean pain scores (0-10 VAS) were 4.53(at rest), 6.09(when gripping), 6.06(when lifting) and 6.42(when turning objects). The mean tender joint count was 7.14 and the mean score for objective soft tissue swelling in the joints was 1.36.

#### Conclusions

From these analysis, we can see that patients are referred very late with no one being seen within 6 months of symptoms onset. This is, in spite of, patients having pain scores which are comparable to those with inflammatory arthritis and in a small minority evidence of soft tissue swelling in joints at the time of presentation. In addition it is noticeable that men are under-represented in the cohort of referred patients based on estimates of prevalence.

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**Humira (adalimumab) 20mg and 40mg solution for injection in pre-filled syringe, Humira 40mg and 80mg solution for injection in pre-filled pen. Refer to Summary of Product Characteristics (SmPC) for full information. Presentation and method of administration:** Each single dose 0.2 ml pre-filled syringe contains 20 mg of adalimumab for subcutaneous injection. Each single dose 0.4 ml pre-filled syringe contains 40mg of adalimumab for subcutaneous injection. Each single dose 0.8 ml pre-filled pen contains 80 mg of adalimumab for subcutaneous injection.

**Indications and Dosage:** Humira 20mg pre-filled syringe and Humira 80 mg pen are only approved for use in specific indications with a therapeutic requirement, **please refer to SmPCs for full information.** Humira treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Humira is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Humira. Patients treated with Humira should be given the Patient Reminder Card. After proper training in injection technique, patients may self-inject with Humira if their physician determines that it is appropriate and with medical follow-up as necessary. During treatment with Humira, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised.

**Rheumatoid arthritis (RA), adults:** In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. **Dosage:** 40 mg single dose every other week (EOW). Concomitant MTX should be continued. In monotherapy, patients may require 40 mg every week or 80mg EOW if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Reintroduction of Humira after discontinuation for 70 days or longer gave same magnitudes of clinical response and similar safety profile as before dose interruption.

**Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above:** In combination with MTX, for active pJIA, with inadequate response to one or more DMARDs. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. **Dosage:** 10 kg to <30 kg: 20 mg EOW. If ≥ 30 kg: 40 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.

**Enthesitis-related arthritis (ERA), paediatrics 6 years and above:** For active ERA with inadequate response or intolerance to conventional therapy. **Dosage:** 15 kg to <30 kg: 20 mg EOW. If ≥ 30 kg: 40 mg EOW.

**Ankylosing spondylitis (AS), adults:** For severe active AS with inadequate response to conventional therapy. **Dosage:** adults: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.

**Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults:** For severe nr-axSpA with objective signs of inflammation (elevated CRP and / or MRI), and an inadequate response to, or intolerance to nonsteroidal anti-inflammatory drugs. **Dosage:** 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.

**Psoriatic arthritis (PsA), adults:** For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. **Dosage:** 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.

**Psoriasis (Ps), adults:** For moderate to severe chronic plaque psoriasis in candidates for systemic therapy. **Dosage:** 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1.

Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Beyond 16 weeks, patients with inadequate response can increase dosage to 40 mg every week or 80mg EOW (refer to SmPC). If adequate response is achieved with 40mg every week or 80mg EOW, dosage may subsequently be reduced to 40 mg every other week.

**Psoriasis, paediatrics 4 years and above:** For severe chronic plaque psoriasis with inadequate response to or if topical therapy and phototherapies are inappropriate. **Dosage:** 15 kg to <30 kg: 20 mg dose initially followed by 20 mg EOW starting one week after initial dose. If ≥ 30 kg: 40 mg dose initially followed by 40 mg EOW starting one week after initial dose. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time.

**Hidradenitis suppurativa (HS), adults and adolescents from 12 years of age:** For active moderate to severe HS (acne inversa) in patients with an inadequate response to conventional systemic HS therapy. **Dosage:** HS, adults: 160 mg dose initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80mg EOW. Reintroduction after treatment interruption: 40 mg every week or 80 mg EOW.

**Dosage:** HS, adolescents from 12 years and ≥30 kg: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. If there is inadequate response to 40 mg EOW, an increase in dosage to 40 mg every week or

80mg EOW may be considered. Treatment interruption: Humira may be re-introduced as appropriate.

Adults and adolescents from 12 years of age: Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions is recommended to be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no improvement in that time. Evaluate periodically the benefit and risk of continued long-term treatment.

**Crohn's disease (CD), adults:** For moderately to severely active CD in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, or are intolerant to or have medical contraindications for such therapies.

**Dosage:** Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If decrease in clinical response, can increase dosage to 40 mg every week or 80mg EOW. Patients with no response by Week 4 may benefit from continued maintenance therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.

**Paediatric Crohn's disease (CD), 6 years and above:** For moderately to severely active CD with inadequate response to, intolerance to or contraindication for conventional therapy including primary nutrition therapy and a corticosteroid, and/or an immunomodulator.

**Dosage:** < 40 kg: Induction: 40 mg dose at Week 0, followed by 20 mg at Week 2. For a more rapid response: 80 mg at Week 0, followed by 40 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 20 mg dose EOW. If insufficient response, consider an increase in dosage to 20 mg every week. If ≥ 40 kg: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.

**Ulcerative colitis (UC), adults:** For moderately to severely active UC with inadequate response to, intolerance to or contraindication for conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). **Dosage:** Induction: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If insufficient response, consider an increase in dosage to 40 mg every week or 80mg EOW. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time.

**Uveitis, adults:** For non-infectious intermediate, posterior and



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**References**

<sup>1</sup>. Burmester GR. et al Ann Rheum Dis. 2009; 68(12): 1863 – 1869

<sup>2</sup>. AbbVie Data on File REF – 36948

<sup>3</sup>. HUMIRA SmPC. Available on [www.medicines.ie](http://www.medicines.ie)

<sup>4</sup>. Commission implementing directive 2012/52/EU of 20 December 2012

<sup>5</sup>. Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2014. SI No. 504 2014

panuveitis with inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **Dosage:** 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Humira. Evaluate on a yearly basis the benefit and risk of continued long-term treatment.

**Paediatric Uveitis, 2 years and above:** For chronic non-infectious anterior uveitis with inadequate response or intolerance to conventional therapy, or in whom conventional therapy is inappropriate. **Dosage:** < 30 kg: 20 mg dose EOW in combination with MTX. Optional 40 mg loading dose one week prior to start of maintenance therapy. No clinical data in use of loading dose < 6 years of age (see SmPC). If ≥ 30 kg: 40 mg dose EOW in combination with MTX. Optional 80 mg loading dose one week prior to start of maintenance therapy. Evaluate on a yearly basis the benefit and risk of continued long-term treatment.

**Contraindications:** Hypersensitivity to the active substance or any of the excipients (see SmPC). Active tuberculosis (TB) or other severe infections such as sepsis and opportunistic infections; Moderate to severe heart failure (NYHA class III/IV).

**Warnings and precautions:** Clearly record trade name and batch number of administered product to improve traceability of biological medicinal products. **Infections:** Patients taking Tumour Necrosis Factor (TNF)-antagonists are more susceptible to serious infections especially if impaired lung function. Monitor for infections, including TB, before, during and for 4 months after treatment. Do not initiate treatment with an active infection, until it is controlled. Consider risk/benefit prior to treatment in patients exposed to high risk of TB or who have travelled in areas of high risk of TB or endemic mycoses. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis, and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections, including the use of concomitant immunosuppressive medications. **Serious infections:** Serious infections, including those with hospitalisation or death reported in patients receiving treatment. **TB:** Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated) reported. Screen all patients before therapy initiation for active or latent TB. Appropriate screening tests (i.e. tuberculin skin test and chest X-ray) should be performed in all patients. If active TB is diagnosed Humira therapy must not be initiated. If latent TB is suspected, consult a physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Humira. Despite prophylaxis, TB

reactivation has occurred on Humira. **Other opportunistic infections:** Opportunistic infections observed in patients receiving Humira. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. **Hepatitis B Reactivation:** Reactivation of HBV has occurred in chronic carriers (surface antigen positive). Patients should be tested for HBV infection before initiating treatment. HBV carriers should consult with a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of Humira. If reactivation occurs stop treatment and initiate appropriate anti-viral and supportive treatment. **Neurological events:** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinuation of treatment should be considered if any of these disorders develop. Neurological evaluation should be performed in patients with non-infectious intermediate uveitis before therapy initiation and regularly during treatment, to assess for pre-existing or developing central demyelinating disorders. **Allergic reactions:** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or anaphylactic reaction, stop Humira immediately and initiate appropriate therapy. **Malignancies and lymphoproliferative disorders:** A possible risk of malignancy, including lymphoma and leukaemia, in all patients including paediatric patients, treated with TNF antagonists. Examine all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment for non-melanoma skin cancer prior to and during treatment, caution in COPD patients, and in patients with increased risk of malignancy due to heavy smoking. Consider the potential risk with the combination of AZA or 6-MP and Humira (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk of developing dysplasia or colon cancer is unknown. Patients with UC, history of dysplasia or colon carcinoma to be screened for dysplasia before and during treatment.

**Haematologic reactions:** Adverse events of the haematologic system reported with Humira. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias develop while on treatment. **Vaccinations:** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to Humira treatment. **Congestive heart failure:** See contraindications. Caution is advised in mild heart failure (NYHA class I/II). Discontinue treatment for new or worsening symptoms of congestive heart failure. **Autoimmune processes:** Autoimmune antibodies may form with Humira. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. **Surgery:** Consider the long half-life of Humira for planned surgical procedures.

Closely monitor for infections. **Small bowel obstruction:** Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture requiring surgical treatment. **Elderly:** Serious infections were higher in patients over 65 years of age, some of which had a fatal outcome. Consider risk of infections in these patients.

**Interactions:** Antibody formation was lower when Humira was given together with MTX in comparison with use as monotherapy. Combination of Humira with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended.

**Fertility, pregnancy and lactation:** Humira should only be used during pregnancy if needed. Women of childbearing potential should consider the use of adequate contraception and continue its use for at least five months after the last Humira treatment. No administration of live vaccines (e.g. BCG) to infants exposed to Humira in utero for 5 months following mother's last Humira treatment during pregnancy. Humira can be used during breast-feeding.

**Adverse Reactions:** Very common ≥ 1/10: Respiratory tract Infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leukopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema).

**Serious, including fatal, adverse reactions have been reported,** including infections/sepsis, TB, opportunistic infections, allergic reactions (including anaphylaxis), HBV reactivation and malignancies (including leukaemia, lymphoma and hepatosplenic T-cell lymphoma). Serious haematological, neurological and autoimmune reactions have also been reported. These include rare reports of pancytopenia, aplastic anaemia, central and peripheral demyelinating events and reports of lupus, lupus-related conditions and Stevens-Johnson syndrome.

**Prescribers should consult the SmPC for the complete list of reported side effects.**

**Legal Category:** POM (S1A).

**Marketing Authorisation Numbers:** EU/1/03/256/022, EU/1/03/256/013, EU/1/03/256/017, EU/1/03/256/021.

**Further information:** available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24.

**HCPs are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).**

**Date of revision of PI:** October 2018, PI/256/024

**Date of preparation:** July 2019, IE-HUM-190030

# Living Well with Arthritis and Related Conditions courses

The Living Well with Arthritis and Related Conditions course is an award-winning workshop that has proven to be an important part of effective arthritis treatment by decreasing pain, reducing reliance on health professionals and medication, and improving overall sense of well-being.

The course is delivered over a six-week period.

The Living Well course will run in 17 locations around the country this autumn. Full details on the website.

**World Arthritis Day  
12 October 2019**



Web [www.arthritisireland.ie](http://www.arthritisireland.ie)  
Email [helpline@arthritisireland.ie](mailto:helpline@arthritisireland.ie)  
Helpline 01 661 8188 or 1890 252 846



Arthritis Ireland



Photos from ISR Spring Meeting 2019



Full audience



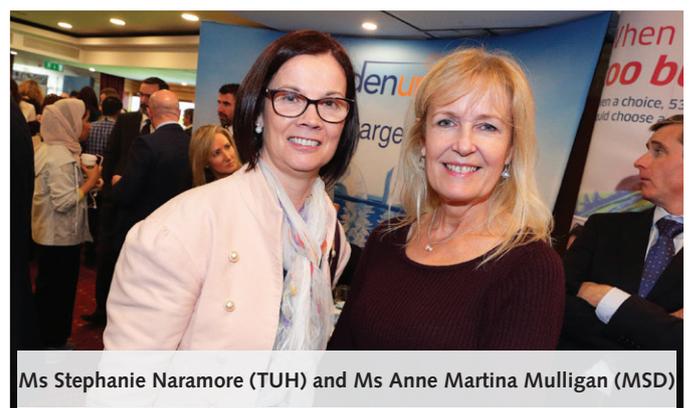
Professor Catherine Nelson Piercy, Speaker



Dr Sinead Harney



Dr Sharon Cowley (Navan) and Dr Aine Gorman (Tullamore)



Ms Stephanie Naramore (TUH) and Ms Anne Martina Mulligan (MSD)



(19A135) ABSTRACT 31

REGULAR POSTER 23

**A review of patients started on Janus Kinase inhibitor (JAKi) in University Hospital Waterford**

**Author(s)**

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**Department(s)/Institutions**

Department of Rheumatology, University Hospital Waterford

**Introduction**

In 2017, Janus Kinase inhibitors (JAKi) were licensed for rheumatoid arthritis (RA) and Psoriatic arthritis PsA: Baricitinib and Tofacitinib. They are licensed for use in patients with high disease activity, with or without methotrexate, following failure of conventional synthetic Disease- Modifying Anti Rheumatic drugs (cs) DMARDs or of at least one biologic DMARD.

**Aims/Background**

To describe the baseline characteristics of patients attending the rheumatology department of University Hospital Waterford prescribed JAKi between July 2018 and March 2019.

**Method**

Information on Demographics, diagnosis, and adverse effects were collected for patients on JAKi.

**Results**

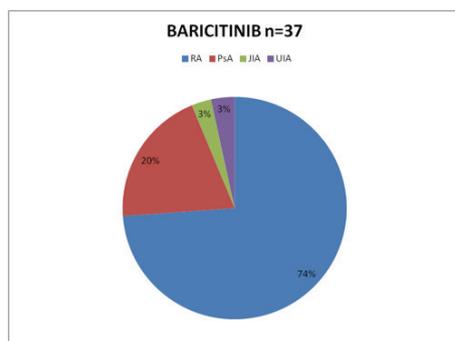
54 patients were started on JAKi during that period. 37 (68%) of them were started on Baricitinib and the remaining 17(32%) on Tofacitinib. Out of 37 patients on Baricitinib, 26 had diagnosis of Rheumatoid Arthritis (RA), 7 Psoriatic Arthritis (PsA), 1 Juvenile Inflammatory Arthritis (JIA) and 2 had Undifferentiated Inflammatory Arthritis. 6 of the 17 patients on Tofacitinib had RA, 8 had PsA and 3 patients Polymyalgia Rheumatica (PMR), (although not licensed), were started on Tofacitinib. 50 of the 54 patients had been on Methotrexate previously. 1 patient had contraindication to Methotrexate. 3 patients with PMR were tried on JAKi as steroid sparing agent. 22 patients were still on Methotrexate with JAKi. 36 patients had received various biologic DMARD with sub optimal response prior to treatment with JAKi. Varicella status was checked in all patients.

Baricitinib was stopped in 2 patients due to ineffectiveness. Both of these patients had advanced sero positive RA and failed multiple therapies. 2 other patients developed Shingles; Baricitinib was withdrawn in both. All others showed good clinical response.

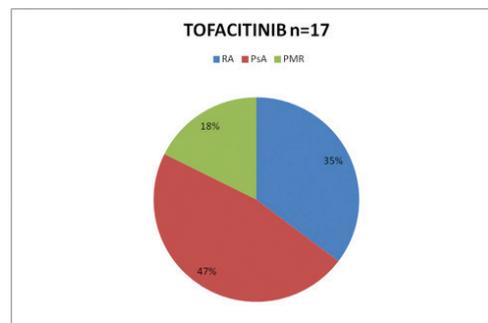
**Conclusions**

To date, more patients have started baricitinib than tofacitinib in our department, possibly likely owing the once daily dosing. Two groups of patients are emerging; those receiving JAKi immediately following csDMARDS failure and those with established disease following multiple biologic DMARDs. Most of the patients in both groups showed good response to JAKi. A limitation of this review is that DAS scores were not recorded pre and post therapy for all patients. Long term follow up needed to see sustained effectiveness.

Figure



Figure



(19A140) ABSTRACT 32

REGULAR POSTER 24

**Skills and attitudes of medical registrars towards patients with rheumatic diseases – a cross-sectional study from a tertiary center**

**Author(s)**

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St. Vincent's University Hospital - Dublin

**Introduction**

Musculoskeletal diseases are a leading cause of disability worldwide and make up to 20% of GP visits. A pilot study in the west of Ireland indicated a prevalence of 40% of rheumatic or musculoskeletal diseases among acutely admitted medical patients. Lack of adequate rheumatology exposure had been cited as the main factor for low skill level among internal medicine and GP trainees

**Aims/Background**

This study aims to identify skill levels and core generic skills gaps for common conditions and therapeutics in rheumatology among a heterogenous group of medical registrars training in various medical specialties at a tertiary center.

**Method**

Online survey format was sent to all medical registrars in SVUH for a period of 1 month during Oct 2018. Rheumatology specialist registrars were assigned as a control group in order to provide a reference for the skill level. Consent was gained by all participants upon voluntary inclusion

**Results**

The survey comprised 23 questions with an average completion time of 2 mins at a response rate of 50% by medical registrars and 70% by rheumatology registrars/ SpRs. Total of 19 medical registrars & 17 rheumatology SpR participated. See table 1 for demographics and self-reported skill levels. The questions covered common areas such as dealing with a flare of RA, SLE, Gout or dealing with anti-TNF drugs during acute illness or starting crucial treatment out of hours when no rheumatology cover available.

**Conclusions**

The study identified poor rheumatology skill level among senior medical trainees due to lack of post-grad experience/ exposure. Rheumatology currently is not regarded as a key specialty for basic training by RCPI. As the prevalence of rheumatic diseases such as osteoarthritis and gout is expected to increase given the changing demographics, next-generation physicians are likely to encounter more populations with such conditions or on newer immunomodulatory therapies, therefore a period of training in rheumatology needs to be encouraged



Figure

Table 1

	Medical registrars N = 19	Control group (Rheum SpRts) N = 17	P value*
Age group, 30-34	63.2%	47.1%	0.096
Gender, female %	63.2%	58.8%	0.790
Experience as registrar in yrs., Mean (SD)	2.89 (1.4)	3.35 (1.5)	0.351

\*Independent t-test or Chi-Square statistics

Self-reported confidence levels

Clinical exam skill score for Arthritis (scale 1-5), (SD)

	Medical registrars N = 19	Control group (Rheum SpRts) N = 17	P value*
Synovitis of hands' small joints	3.68 (0.58)	4.35 (0.61)	0.002
Synovitis wrists	3.32 (0.89)	4.35 (0.61)	<0.001
Synovitis Elbows	3.21 (0.79)	4.00 (0.61)	0.002
Synovitis Knees	3.58 (0.9)	4.59 (0.62)	<0.001
Synovitis of feet's MTPs	2.95 (0.85)	3.76 (0.75)	0.004
Recognizing a gouty tophus	4.05 (0.62)	4.41 (0.71)	0.119
Testing for rotator cuff/shoulder impingement	2.37 (1.01)	4.12 (0.78)	<0.001

History taking skill score (scale 1-5), SD

	Medical registrars N = 19	Control group (Rheum SpRts) N = 17	P value*
Recognizing Inflammatory LBP	2.63 (0.76)	4.18 (0.72)	<0.001
Inflammatory Vs Mechanical joint problem	3.28 (0.93)	4.12 (0.86)	0.007

Procedures

	Medical registrars N = 19	Control group (Rheum SpRts) N = 17	P value*
Performing Knee Aspiration	2.63 (1.2)	3.88 (0.70)	<0.001

\*Independent t-test

Figure

Table 1 Patient's characteristics stratified by diagnosis

	Inflammatory Arthritis	Non-inflammatory Arthritis	P value*
Number	41	51	-
Age, mean (SD)	47.6 (18.1)	53.4 (15.9)	0.114
Female %	75.6	78.4	0.749
BMI, mean (SD)	26.99 (5.4)	27.3 (5.8)	0.788
Co-morbidities %	53.7	64.1	0.060
Active smoking %	4.9	7.8	0.648
Duration of symptoms (months), median (range)	6 (1-60)	12 (1-120)	0.162
Waiting time to clinic (months), median (range)	2 (0-9)	3 (1-10)	0.054
RF positive %	56.1	22	0.002
ACPA positive %	36.6	3.9	0.000
Erosive %	17.1	3.9	0.012
Discharged 1st visit %	0	37.3	0.000
Discharged at 12 months %	12.2	54.2	0.000
CRP (mg/l) 1 <sup>st</sup> visit, median (range)	5.5 (1-51)	1 (1-26)	0.000
ESR (mm/h) 1 <sup>st</sup> visit, median (range)	20 (2-74)	6 (2-93)	0.000
Diagnosis changed at 12 months %	12.2	8	0.540
Steroids prescribed 1 <sup>st</sup> visit %	48.8	8%	0.000
NSAIDs prescribed 1 <sup>st</sup> visit %	2.4	16	0.031
In remission / LDA at 12 months	73.2	70	0.432
DMARDs started initial visit %	31.7	0	0.000
DMARDs started subsequent visits %	42.5	12.2	0.001

\*Independent t-test or Chi-Square X<sup>2</sup> statistics

(19A141) ABSTRACT 33

REGULAR POSTER 25

Profile and outcomes of early arthritis clinic patients: a tertiary referral center experience

Author(s)

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Introduction

Rapid access to specialist care and early treatment with disease-modifying anti-rheumatic drugs (DMARDs) is crucial to prevent poor outcomes. Early identification of patients with Inflammatory Arthritis (IA) can be achieved through the early arthritic clinic (EAC). EULAR recommends that patients with suspected early arthritis should be referred to and seen by a rheumatologist within 6 weeks of symptoms onset.

Aims/Background

To describe demographic, clinical & immunological characteristics of a cohort referred to our well established EAC together with their outcome at 12 months.

Method

retrospective review to all patients referred to the EAC between Jan-June 2016 was conducted. Data collected included co-morbidities, the pattern of conventional and/or biological DMARDs uptake, rate of steroids/ NSAIDs prescribing, rate of requested diagnostic imaging, frequency of IA diagnoses, discharge to primary care & the waiting time to see a rheumatologist.

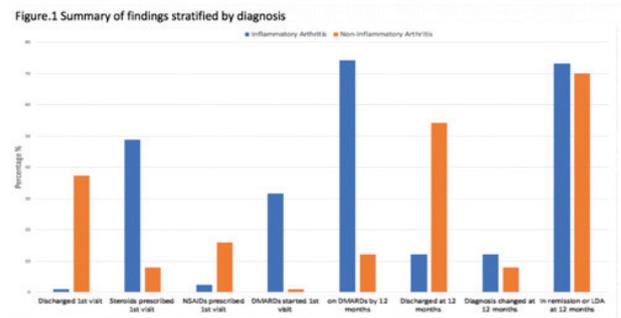
Results

113 patients attended our EAC during the study period. 21 were excluded (only re-linked to service). 92 patients underwent full assessment as newly referred patients to attend rheumatologist for the first time. The mean age is 50.8 years, 77.2 % were females with a mean BMI of 27.18. Patients had a median duration of symptoms for 7.5 months with a median waiting time to see rheumatologist of 2 months. See table 1.

Conclusions

EAC is an efficient platform which provides rapid access for specialist assessment for early IA identification, early DMARDs and high discharge rate to those don't require ongoing specialist care.

Figure



(19A143) ABSTRACT 34

REGULAR POSTER 26

Cost Effectiveness and Efficacy of Reduced Dose Rituximab Biosimilar in a Seropositive Rheumatoid Arthritis DMARD resistant cohort

Author(s)

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St. James's Rheumatology Department

Introduction

Low dose rituximab (2x500mg) has been shown to be non-inferior to the original approved dose (2x1000mg) in seropositive rheumatoid arthritis refractory to conventional DMARDs.

Aims/Background

This study assesses the real world application and pharmacoeconomic implications of rituximab biosimilar Truxima at reduced dose of 2x500mg infusions in a small cohort of ACA positive patients.

Method

The patient cohort consisted of DMARD refractory RA patients who were either previously treated with the original licenced dose of 1000mg or biologic naïve. It consisted of 14 patients in total, 3 male and 11 female, with an age range of 49 to 85 and median of 68. To date, 3 of 14 patients have failed reduced dose Truxima treatment at the usual 6 monthly 2x500mg infusions. Failure was defined as lack of clinical efficacy as defined by DAS28CRP score.



**Results**

Of note reduced dose Truxima successfully depleted B Cells in all 3 patients deemed to have relapsed. In the first relapse case flow cytometry demonstrated a depleted B Cells but a normal T Cell population. It was decided to administer a further 1g Truxima infusion. In the second relapse case flow cytometry revealed depleted B Cells and a low T Cell population. It was also decided to administer a further 1g Truxima infusion. In the third relapse flow cytometry showed depleted B Cells and normal T cell population. It was deemed safe to switch treatment and commence abatacept to inhibit the T Cell pathway.

**Conclusions**

Within this small cohort, results to date show successful B cell depletion with reduced dose rituximab biosimilar comparable to conventional full dose. It is known that B cells play a role in stimulating T cell activation in synovium through expression of co-stimulatory molecules. However ongoing flow cytometry B and T cell population analysis demonstrates that B cell depletion alone does not always maintain clinical remission and may be used to aid decision making in switching biologic classes.

From the pharmacoeconomic perspective, the first 12 courses of treatment, where each course consisted of two 500mg Truxima infusions two weeks apart, has saved €33,475 over the first 10 months of investigation.

(19A144) ABSTRACT 35

REGULAR POSTER 27

**RHEUM TO IMPROVE – A Study on Rheumatology Knowledge Amongst Medical Students**

**Author(s)**

Wan Lin Ng, Joe Devlin, Alexander Fraser

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**Introduction**

Medical students are tomorrow’s doctors. Teaching in medical schools provides a core platform for future skills, practice and knowledge. Rheumatology seems to be losing its status in school curricula despite its rise in importance.

**Aims/Background**

To determine the knowledge of common rheumatic diseases amongst Year 3 graduate-entry medical students(GEMS) before and after a session of rheumatology tutorial.

**Method**

19 GEMS who were soon to sit for Year 3 final examination were asked to complete questionnaires pre and post rheumatology tutorial regarding their knowledge and confidence in examining/managing rheumatic diseases namely rheumatoid arthritis(RA), psoriatic arthritis(PsA), osteoarthritis(OA), gout, systemic lupus erythematosus(SLE), scleroderma and ankylosing spondylitis(AS). Knowledge and confidence were measured using a 5-point Likert scale.

**Results**

Students were aged 21-30 years. None had previous rotation in rheumatology but 2(10.5%) had attended a rheumatology clinic before. All were not completely confident in examining the seven rheumatic conditions. >50% were somewhat or fairly confident in examining patients with RA, PsA, OA and gout. The majority found themselves either slightly or not confident in examining SLE, scleroderma and AS patients.

Only one stated to have excellent knowledge on the treatment/management of one rheumatic condition, which was gout. 80% or more have above average knowledge on treatment/management of RA, OA and gout. 47.4% rated their knowledge to be poor in the treatment/management of PsA and SLE. Knowledge on treatment/management of scleroderma and AS was below average in >84%.

Following a rheumatology tutorial, everyone had confidence in

examining all seven rheumatic diseases. 78.9% and above were either fairly or completely confident in examining patients with RA, PsA, OA, gout, scleroderma and AS versus 52.6% for SLE. All were above average in treating/managing RA, PsA, OA and gout. 78.9% or more have above average knowledge in treatment/management conditions like SLE, scleroderma and AS.

Everyone who attended the tutorial felt that it contributed positively in their preparation towards examination and would like to have similar tutorials in future.

**Conclusions**

Knowledge in examining, treating and managing common rheumatic diseases is very poor amongst medical students. Rheumatology tutorials are beneficial to increase their knowledge and confidence. Attendance in rheumatology clinics should also be encouraged.

Figure

Table 1: Confidence in examining patients with common rheumatic conditions pre and post rheumatology tutorial

	Not confident at all (Pre, Post)	Slightly confident (Pre, Post)	Somewhat confident (Pre, Post)	Fairly confident (Pre, Post)	Completely confident (Pre, Post)
Rheumatoid arthritis	0,0	0,1	10,0	9,11	0,7
Psoriatic arthritis	3,0	2,1	10,1	4,13	0,4
Osteoarthritis	0,0	0,1	8,0	11,11	0,6
Gout	1,0	3,1	8,1	7,12	0,5
Systemic Lupus Erythematosus	5,0	7,4	5,5	2,9	0,1
Scleroderma	11,0	3,2	4,1	1,15	0,1
Ankylosing Spondylitis	10,0	5,1	3,3	1,12	0,3

Figure

Table 2: Knowledge on basic management/treatment of patient with common rheumatic conditions pre and post rheumatology tutorial

	Very poor (Pre, Post)	Poor (Pre, Post)	Average (Pre, Post)	Good (Pre, Post)	Excellent (Pre, Post)
Rheumatoid arthritis	0,0	2,0	9,2	8,12	0,5
Psoriatic arthritis	0,0	9,0	6,5	4,10	0,4
Osteoarthritis	0,0	1,0	5,4	12,10	1,5
Gout	0,0	3,0	6,2	10,13	0,4
Systemic Lupus Erythematosus	0,0	9,4	10,7	0,6	0,2
Scleroderma	5,1	11,2	3,4	0,10	0,2
Ankylosing Spondylitis	4,1	13,1	2,5	0,10	0,2

(19A145) ABSTRACT 36

REGULAR POSTER 28

**Adherence by patients on Methotrexate to getting the advised regular laboratory tests done**

**Author(s)**

Salamat Ali, Arslan Ather, Ursula Bond, Eleanor Dunlee, Michael Regan

**Department(s)/Institutions**

South Infirmary Victoria University Hospital, Cork

**Introduction**

Arthritis still remains the biggest cause of disability and major cost on healthcare system. In Ireland 18% of population under age of 55. Three quarters of patients are in working age. Methotrexate is used as the anchor drug in the treatment of Inflammatory Arthritis. Methotrexate causes bone marrow suppression, liver parenchymal toxicity and renal toxicity. Therefore, all patients who are put on Methotrexate are advised by Consultant /team NCHD at each visit to clinic that they need regular monitoring with laboratory tests at designated intervals. They also receive education about Methotrexate and importance of monitoring labs by Rheumatology Specialist Nurse.

**Aims/Background**

To determine the level of compliance with blood monitoring as advised at the clinic visit when MTX was first started, as well as is advised at all subsequent visits to clinic, in accordance with ACR/BSR guidelines & local protocols, in order to detect abnormalities early on and thus prevent adverse affects of MTX on the liver, kidney



and bone marrow.

#### Method

Data was collected from 50 consecutive patients at follow-up visits at Rheumatology clinics in South Infirmiry-Victoria University Hospital over a 3-month period from 1st October 2018 to 31st December 2018. After consent, the patient was interviewed & a questionnaire was filled for data collection taken together with evidence of such lab monitoring from the i-lab system and blood reports gotten from their GP.

#### Results

Data was collected from 50 consecutive patients: 44 patients (88%) were compliant with the advised laboratory monitoring regularity as was clearly advised to them at their clinic visits & clinic letter sent to their GP. Out of 50, only 6 patients (12%) were non-compliant with laboratory monitoring.

#### Conclusions

The audit shows that the vast majority of patients on Methotrexate (88%) are fully compliant with laboratory monitoring while only 12% are not. We can now look at how can we increase this percentage in order to try and get it as near as possible to 100%.

#### (19A147) ABSTRACT 37

#### REGULAR POSTER 29

### A Reaudit on Uptake of Pneumococcal and Influenza Vaccination Status in Patients on Biological Dmards

#### Author(s)

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#### Department(s)/Institutions

Department of Rheumatology, University Hospital Limerick

#### Introduction

BDMARDS have been the panacea for rheumatic diseases but their use may increase the risk of infection.

#### Aims/Background

Morbidity and mortality in patients with chronic disease can be prevented with pneumococcal and influenza vaccinations. EULAR recommended that pneumococcal and influenza vaccination should be considered in patients with autoimmune inflammatory rheumatic diseases<sup>1</sup>.

#### Method

Patients on bDMARDS attending the rheumatology infusion unit were asked about their vaccination status on pneumococcal and influenza using a questionnaire. This re-audit was performed on 62 patients who did not have their pneumococcal and/or influenza vaccination the previous year. These patients were educated and were given Arthritis-UK booklet on vaccination. The patients' current bDMARD, reasons for not having vaccination and number of hospital admissions secondary to infections were recorded.

#### Results

62 patients who did not receive both vaccinations last year were recruited and 45(72.6%) were females. 16(25.8%) had received both pneumococcal and influenza vaccination, 18(29%) had receive influenza vaccination alone, 5(8.1%) had received pneumococcal vaccination alone and 23(37.1%) had neither. 6(9.7%) had hospital admissions due to infections, of which 3 had chest infections, 1 had urinary tract infection, 1 had cellulitis and 1 had necrotising fasciitis. 3 of 12 patients age  $\geq 65$  years received both vaccination. 31(50%) were on rituximab, 28(45.2%) on infliximab and 3(4.8%) on tocilizumab.

Of the 41(66.1%) patients who did not receive the pneumococcal vaccine, 12(29.3%) were not aware of the availability of this vaccine, 8(41.2%) had forgotten to vaccinate, 7(17.1%) were not aware that

it was recommended, 7(17.1%) were afraid of side effects, 4(9.8%) were not interested and 2(4.9%) declined vaccination and 1(2.4%) had a life-threatening infection (necrotising fasciitis). 34(54.8%) received influenza vaccination and for those who didn't, 9(26.5%) were afraid of side effects, 7(20.6%) had forgotten, 6(2.9%) were not interested, 3(8.8%) decline vaccination, 1(2.9%) wasn't aware of its availability, 1(2.9%) wasn't aware that the vaccine was recommended and 1(2.9%) had a life-threatening infection (necrotising fasciitis).

#### Conclusions

Although the re-audit showed below-satisfactory vaccination rates, it demonstrated improvement in patient awareness and vaccination uptake following education. Patients should be educated by primary care physicians and rheumatology staff to increase awareness and alleviate fears of vaccination.

#### (19A149) ABSTRACT 38

#### REGULAR POSTER 30

### Adherence with advice to stop smoking in patients with Inflammatory Arthritis on Methotrexate.

#### Author(s)

Salamat Ali, Arslan Ather, Eleanor Dunlee, Ursula Bond, Michael Regan

#### Department(s)/Institutions

South Infirmiry Victoria University Hospital, Cork

#### Introduction

The patients with diagnosis of IJD, who commenced on Methotrexate are advised to stop smoking by Consultant/NCHD. They receive education about methotrexate and lifestyle changes by Rheumatology Specialist nurse.

#### Aims/Background

To determine level of adherence with advice given to stop smoking at first as well as subsequent visits in accordance with ACR/BSR guidelines & local protocols to ensure compliance to facilitate complete remission.

#### Method

Data was collected from 50 consecutive patients at follow-up visits at Rheumatology clinics in SIVUH over a 3-month period from 1st October 2018 to 31st December 2018. After consent, the patient was interviewed & a questionnaire was filled for data collection.

#### Results

The results are as follows:

Ex-Smoker/Non-Smoker on 1st Clinic : 72%

% of Smokers at 1st visit: 28 % (Target patients )

% of Target Patients Stopped smoking : 36 %

% of Target Patients reduced smoking : 50%

Non-Compliant with advice : 14%

#### Conclusions

The audit shows that the vast majority of patients (86%)are either fully or partially compliant with advice while only 14% are not. We can devise strategies to get it as near as possible to 100%.



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Please refer to the Summary of Product Characteristics for further information.

**Composition:** Each 0.8 ml single dose pre-filled syringe or pre-filled pen contains 40 mg of adalimumab. **Indications:** **Rheumatoid Arthritis (RA):** Moderate to severe active RA in adults, in combination with methotrexate (MTX) treatment, when response to disease-modifying anti-rheumatic drugs (DMARDs), including MTX (unless contraindicated), has been inadequate. Severe, active and progressive RA in adults, in combination with MTX treatment, in adults without prior MTX treatment. **Juvenile Idiopathic Arthritis (JIA):** Active polyarticular JIA, in combination with MTX treatment, in patients from 2 years of age with inadequate response to one or more DMARDs. Active enthesitis-related arthritis (ERA) in patients from 6 years of age who have had an inadequate response to, or who are intolerant of, conventional therapy. **Axial Spondyloarthritis: Ankylosing spondylitis (AS):** Adults with severe, active AS who have had an inadequate response to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA):** Adults with severe nr-axSpA with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or Magnetic Resonance Imaging (MRI), who have had an inadequate response to, or are intolerant to, nonsteroidal anti-inflammatory drugs (NSAIDs). **Psoriatic Arthritis (PsA):** Active and progressive PsA in adults when the response to previous DMARD therapy has been inadequate. **Psooriasis:** Moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy. **Paediatric Plaque Psoriasis (pPP):** Severe chronic plaque psoriasis in patients from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. **Hidradenitis suppurativa (HS):** Active moderate to severe HS (acne inversa) in adults and adolescents from 12 years of age with inadequate response to conventional systemic HS therapy. **Adult Crohn's Disease (CD):** Moderately to severely active CD in adults who have not responded to a corticosteroid and/or an immunosuppressant, or who are intolerant to, or have medical contraindication for such therapies. **Paediatric Crohn's Disease (pCD):** Moderately to severely active CD in paediatric patients from 6 years of age, who have not responded to conventional therapy. **Ulcerative Colitis (UC):** Moderately to severely active UC in adults with inadequate response to conventional therapy or who are intolerant to, or have medical contraindications for such therapies. **Uveitis:** Non-infectious intermediate, posterior and panuveitis in adults with inadequate response to corticosteroids. **Paediatric Uveitis (pU):** chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Administration and dosage:** By subcutaneous injection. Other concomitant therapies such as corticosteroids and/or immunomodulatory agents should be optimised. **Adults: RA:** single 40 mg dose every other week. MTX should be continued during treatment. Monotherapy patients who experience a decrease in response may benefit from 40 mg every week, or 80 mg every other week. If no response within 12 weeks, continued therapy should be reconsidered. **Axial Spondyloarthritis: AS, nr-axSpA, and PsA:** 40 mg every other week. If no response within 12 weeks, continued therapy should be reconsidered. **Psooriasis:** 80 mg in week 1 followed by 40 mg every other week from week 2. If no response after 16 weeks, continued therapy should be reconsidered. If inadequate response beyond 16 weeks, 40 mg every week can be considered, or 80 mg every other week. **HS:** 160 mg at Day 1 (given as four 40 mg injections in one day or two 40 mg injections/day for two consecutive days), followed by 80 mg two weeks later at Day 15 given as two 40 mg injections in one day. From day 29, 40 mg every week, or 80 mg every other week (two 40 mg injections in one day). Antibiotics may be continued during treatment if necessary. If no response within 12 weeks, continued therapy should be reconsidered. Continued long-term treatment should be periodically evaluated. **CD:** Induction: 80 mg at week 0 and 40 mg at week 2. For a more rapid response: 160 mg at week 0 (four 40mg injections in one day or two 40mg injections/day for two consecutive days), and 80 mg at week 2 (two 40 mg injections in one day); risk of adverse events may be higher with

higher induction dose. Maintenance: 40 mg every other week. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Patients with decreased response to 40 mg every other week may benefit from 40 mg every week, or 80 mg every other week. If no response by week 4, benefit may be seen from continued maintenance therapy through week 12. If no response within 12 weeks, continued therapy should be reconsidered. **UC:** Induction: 160 mg at week 0 (four 40 mg injections in one day or two 40 mg injections/day for two consecutive days) and 80 mg at week 2 (two 40mg injections in one day). Maintenance: 40 mg every other week. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Patients with decreased response may benefit from 40 mg every week, or 80 mg every other week. If there is no response after 2-8 weeks, treatment should be discontinued. **Uveitis:** 80 mg initial dose, followed by 40 mg every other week starting one week after the initial dose. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice. Continued long-term treatment should be evaluated on a yearly basis. **Dose adjustments in specific populations: Paediatrics:** Where less than a full 40 mg dose is required, alternative adalimumab products offering the correct dose should be used. **JIA:** For patients with polyarticular JIA from age 2 yrs, dose is based on body weight (see SmPC, Table 1 for dosing). **ERA:** From 6 years of age, dose is based on body weight (see SmPC, Table 2 for dosing). **pPP:** From 4-17 years of age, dose is based on body weight (see SmPC, Table 3 for dosing). It is not possible to dose patients above 4 years of age with a weight less than 30 kg with this product. If no response after 16 weeks, continued therapy should be reconsidered. **Adolescent HS:** From 12 years of age, weighing at least 30 kg, the recommended dose based on pharmacokinetic modelling and simulation is 80 mg at week 0 followed by 40 mg every other week starting at week 1. If inadequate response, 40 mg every week, or 80 mg every other week can be considered. Continued long-term treatment beyond 12 weeks should be periodically evaluated. **pCD:** From 6-17 years of age, dose is based on body weight (see SmPC Table 4 for dosing). Patients  $\geq$  40 kg with insufficient response may benefit from 40 mg every week, or 80 mg every other week. **pU:** From 2 years of age, dose is based on body weight (see SmPC, Table 5 for dosing). No experience without concomitant treatment with methotrexate. For paediatric JIA, HS, and CD, if no response within 12 weeks, continued therapy should be reconsidered. **Contraindications:** Hypersensitivity to the active substance or excipients listed in the SmPC. Active tuberculosis or other severe infections such as sepsis, and opportunistic infections. Moderate or severe heart failure (NYHA class III/IV). **Warnings and Precautions:** Please refer to the SmPC for the full list of Warnings and Precautions. Patients treated with IMRALDI should be given the Patient Reminder Card. **Serious infections:** Do not start IMRALDI during an active infection until infections are controlled. If an infection develops, monitor carefully, and stop IMRALDI if infection becomes serious. **Tuberculosis (TB):** All patients must be evaluated for both active and inactive TB before initiation of treatment. If diagnosed with active TB IMRALDI must not be initiated. **Hepatitis B virus (HBV) reactivation:** Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop IMRALDI and begin anti-viral therapy. **Demyelinating disease (Neurological events):** Exacerbation or new onset, may occur. Consider discontinuation if these disorders develop. **Anaphylaxis or serious allergic reactions** may occur, administration of IMRALDI should be discontinued. **Malignancies:** Incidence of malignancies was greater in IMRALDI-treated patients than in controls. **Haematologic reactions:** Discontinuation of IMRALDI therapy should be considered in patients with confirmed significant haematologic abnormalities. **Vaccinations:** Patients may receive concurrent vaccinations, except for live vaccinations which should not be given. Paediatric patients should be brought up to date with all immunisations prior to initiating IMRALDI. **Heart failure:** Worsening or new onset may occur. **Autoimmune Processes:** If symptoms of

lupus-like syndrome develop; further treatment with IMRALDI should not be given. **Concurrent administration of biological DMARDs or TNF antagonists:** Concomitant administration of IMRALDI with other biological DMARDs or other TNF antagonists is not recommended due to increased risk of infections, including serious infections. **Small bowel obstruction:** Failure to respond to treatment for Crohn's disease may indicate the presence of fixed fibrotic stricture that may require surgical treatment. **Elderly ( $\geq$  65 years):** Particular attention regarding the risk for infection should be paid when treating the elderly. **Excipients with known effects:** Patients with rare hereditary problems of fructose intolerance should not take this medicinal product. **Interactions:** See SmPC. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last IMRALDI treatment. Adalimumab should only be used during pregnancy if clearly needed. Administration of live vaccines (e.g. BCG vaccine) to infants exposed to adalimumab in utero is not recommended for 5 months following the mother's last adalimumab infusion during pregnancy. No effects on the breastfed newborns/infants are anticipated. Concurrently, adalimumab can be used during breastfeeding. **Undesirable effects: Very common:** Respiratory tract infections, leucopenia, anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash, musculoskeletal pain, injection site reaction. **Common:** Systemic infections, intestinal infections, skin and soft tissue infections, ear infections, oral infections, reproductive tract infections, urinary tract infections, fungal infections, joint infections, skin cancer excluding melanoma, benign neoplasm, leucocytosis, thrombocytopenia, hypersensitivity, allergies, hypokalaemia, uric acid increased, blood sodium abnormal, hypocalcaemia, hyperglycaemia, hypophosphatemia, dehydration, mood alterations, anxiety, insomnia, paraesthesia, migraine, nerve root compression, visual impairment, conjunctivitis, blepharitis, eye swelling, vertigo, tachycardia, hypertension, flushing, haematoma, asthma, dyspnoea, cough, GI haemorrhage, dyspepsia, gastroesophageal reflux disease, sicca syndrome, worsening or new onset of psoriasis, uctaria, bruising, dermatitis, onychoclasis, hyperhidrosis, alopecia, pruritus, muscle spasms, renal impairment, haematoma, chest pain, oedema, pyrexia, coagulation and bleeding disorders, autoantibody test positive, blood lactate dehydrogenase increased, impaired healing. **Serious adverse reactions:** Serious infections (refer to SPC for full list), malignancies, haematological reactions (pancytopenia, aplastic anaemia), demyelinating disorders, lupus, lupus-related conditions, Stevens-Johnson syndrome. Please refer to SmPC for full list. **Legal Classification:** POM. **Pack Size:** IMRALDI is available in packs of 2. **Package Quantities:** IMRALDI 40 mg solution for injection in pre-filled syringe (PFS): 0.8 ml solution for injection in single-use pre-filled syringe. IMRALDI 40 mg solution for injection in pre-filled pen (PPF): 0.8 ml solution for injection in single-use pre-filled pen for patient use containing a pre-filled syringe. **Marketing Authorisation Numbers:** PFS 2-pack EU/1/17/1216/002, PPF 2-pack EU/1/17/1216/006. **Marketing Authorisation Holder:** Samsung Bioepis NL B.V, Olof Palmestraat 10, 2616 LR Delft, The Netherlands. Manufacturer: Biogen (Denmark) Manufacturing ApS, Biogen Allé 1, 3400 Hillerød, Denmark. **Further information:** available on request from Biogen MI (see details below). **Date of last revision of Prescribing Information:** May 2019

### Adverse events should be reported.

**Ireland:** Adverse events can be reported to HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie. Adverse events should also be reported to Biogen Idec (Ireland) Ltd. Tel: +353(0)1513 33 33; Email: Medinfo\_biogen@quintiles.com

### Reference:

- Medicines Management Programme Best-Value Biological Medicines: Tumour Necrosis Factor- $\alpha$  Inhibitors on the High Tech Drug Scheme 2nd May 2019
  - BIOGEN Q2 2019 earnings presentation
- <sup>†</sup> Medicines Management Programme

Biogen-22403 Date of Preparation August 2019 IE

▼ This medicinal product is subject to additional monitoring.





(19A150) ABSTRACT 39

REGULAR POSTER 31

**A Network Meta-Analysis to Evaluate the Efficacy of Baricitinib and Other Treatments of Rheumatoid Arthritis in Patients who Are Inadequate Responders to Methotrexate**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

Baricitinib (BARI), an oral, selective inhibitor of Janus kinase (JAK)1/2, is used to treat moderate to severe rheumatoid arthritis (RA) in adults.

**Aims/Background**

To assess the comparative effectiveness of BARI 4-mg (background MTX) and other targeted synthetic/biologic disease modifying anti-rheumatic drugs in moderate-to-severe RA patients with inadequate response to methotrexate (MTX-IR).

**Method**

A systematic literature review (SLR) of randomized controlled trials (RCTs; Phase 3) of interventions of interest was conducted (1999 to 2017) in Medline, Medline In-Process, Embase, Biosciences Information Service, the Cochrane Library, and trials registers. Network meta-analyses (NMAs) of RCTs reporting the American College of Rheumatology (ACR) response data were conducted using Bayesian mixed-treatment comparisons. Here, we present main results for the 24-week ( $\pm 4$ ) time point (fixed-effects simultaneous models).

**Results**

Totally, 24 trials met the SLR inclusion criteria. Analyses, using BARI RA-BEAM trial data, showed BARI 4 mg (background MTX) to be more effective than adalimumab (ADA) 40-mg (EOW; odds ratio [OR] 1.33; 95% credible interval [CrI] 1.01-1.75), abatacept (ABA) 10-mg (IV/4 weeks; OR 1.47; 95%CrI 1.02-2.13), and infliximab 3-mg (IV/8 weeks; OR 1.61; 95%CrI 1.12-2.27) for ACR20. While no differences were found on ACR50, BARI 4-mg (background MTX) was found to be more effective than ADA 40-mg (OR 1.39; 95%CrI 1.02-1.89), ABA 10-mg (OR 1.85; 95%CrI 1.09-3.23), rituximab (RTX) 1000-mg (OR 2.38; 95%CrI 1.10-5.00) and 2000-mg (OR 2.44; 95%CrI 1.04-5.56) for ACR70. BARI 4-mg (background MTX) showed better results than etanercept monotherapy (50 mg/week or 25 mg/biweekly; OR 2.27; 95%CrI 1.04-5.26) for ACR20, and RTX 1000-mg monotherapy for ACR20/ACR70 (OR 1.82; 95%CrI 1.02-3.13)/(OR 2.70; 95%CrI 1.04-7.14). Sensitivity analysis including 10 additional trials with up to 20% of patients with prior biologic use allowed comparison versus tofacitinib (TOFA), showing BARI 4-mg (background MTX) is more effective than TOFA 5 mg (BID) monotherapy for ACR20 (OR 1.92; 95%CrI 1.32-2.86).

**Conclusions**

The comparative analyses support BARI as an efficacious treatment option for moderate-to-severe RA patients with MTX-IR.

Previously presented at ISPOR-EU (2018).

(19A151) ABSTRACT 40

REGULAR POSTER 32

**Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis up to 7 Years: An Updated Integrated Safety Analysis**

**Author(s)**

Mark C Genovese<sup>1</sup>, Josef S Smolen<sup>2</sup>, Tsutomu Takeuchi<sup>3</sup>, Gerd Burmester<sup>4</sup>, Dennis Brinker<sup>5</sup>, Terence P Rooney<sup>5</sup>, Jinglin Zhong<sup>6</sup>, Daojun Mo<sup>5</sup>, Chadi Saifan<sup>5</sup>, Anabela Cardoso<sup>5</sup>, Maher Issa<sup>5</sup>, Wen-Shuo Wu<sup>5</sup>, Kevin L Winthrop<sup>7</sup>

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**Introduction**

Baricitinib (BARI), an oral, selective inhibitor of Janus kinase (JAK)1/2, is used to treat moderate to severe rheumatoid arthritis (RA) in adults.

**Aims/Background**

We describe the drug's safety profile with updated data from an additional Phase (Ph) 3 trial and an on-going long-term extension (LTE) study.

**Method**

Long-term safety of once-daily BARI was evaluated in the All-BARI-RA dataset: all patients (pts) exposed to BARI from 9 randomized trials (5 Ph3, 3 Ph2, 1 Ph 1b) and 1 LTE (data to February 13, 2018). Placebo (PBO) comparisons were evaluated to Week 24 from 7 Ph2/3 trials: pts randomized to PBO, BARI 2-mg or 4-mg, with censoring at rescue/treatment switch. Dose responses were evaluated in the 2-mg/4-mg extended dataset from 4 Ph2/3 trials: pts randomized to 2-mg or 4-mg, LTE data included; data censored at rescue/dose change (as-treated analysis) and analyzed without censoring (as-randomized analysis). Incidence rates (IRs) per 100 patient-years (PY) were calculated.

**Results**

Totally, 3770 pts received BARI (10,127 PYs); maximum exposure was 7 years. No significant differences were seen for BARI 4-mg vs PBO in adverse events leading to permanent drug discontinuation, death, malignancy, serious infection, or major adverse cardiovascular events. Herpes zoster IR was significantly higher for BARI 4-mg than PBO (3.8 vs 0.9) and numerically higher for BARI 2-mg (3.1). The IRs for deep vein thrombosis/pulmonary embolism were numerically higher in BARI 4-mg than PBO; IRs were similar by dose in 2-mg/4-mg extended dataset. Malignancy (excluding non-melanoma skin cancer) IRs were 0.8 (2 mg) and 1.0 (4 mg; as-randomized analysis). Fewer than 1% pts discontinued for abnormal laboratory results.

**Conclusions**

BARI maintained a safety profile similar to that previously reported and acceptable in the context of demonstrated efficacy.

Previously presented at EULAR (2019).



(19A156) ABSTRACT 41

REGULAR POSTER 33

**CD209+/CD14+ dendritic cells characterization in rheumatoid vs psoriasis arthritis**

**Author(s)**

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**Introduction**

Dendritic cells (DCs) are a heterogeneous population of professional antigen-presenting cells which are at the interface between innate and adaptive immunity. There are different DCs subsets which are classified according to their tissue location and their functions. A specific subset of DCs is known to derive from monocyte and have a key role in inflammation and infection.

**Aims/Background**

This study firstly aimed to identify and characterize a specific subset of DC CD209+/CD14+ and evaluate their characteristics at the periphery of inflammatory arthritic patients (IA). In addition, it aimed to evaluate the enrichment and activation of the specific DC subset at the site of inflammation, the joint of IA patients.

**Method**

Peripheral blood and synovial fluid mononuclear cells (PBMC and SFMC) were isolated by Ficoll density gradient from healthy subject (HC), rheumatoid (RA) and psoriatic (PsA) arthritic patients. Single cell biopsy suspension from RA and PsA patients was obtained by enzymatic digestion. PBMC, SFMC and biopsy suspension were analysed by flow cytometry to identify the CD209+/CD14+ DC subset and its frequency (HLADR+/CD11c+). Chemokines receptors expression on the CD209+/CD14+ DC subset were also evaluated by flow cytometry.

**Results**

We identified the CD209+/CD14+ DC population in PBMC of RA and PsA patients and we observed that this population was enriched in SFMC of RA and PsA patients, with a further percentage increase in the synovial tissue cell suspension. In addition we identified a differential expression of chemokine receptors at the periphery of RA and PsA patients, when compared to the HC, with increased expression of CCR7 and decreased expression of CXCR3. This observation suggest that DCs are already activated and migratory in the periphery of IA patients. We further observed a unique profile of chemokines receptors in the synovial tissue cell suspension of RA and PsA patients, with an increased expression of CCR7 and CXCR3/5.

**Conclusions**

We identify for the first time in the periphery of RA and PsA patients the monocyte-derived DC population CD209+/CD14+ DC. This population was enriched at the site of inflammation and displayed a unique chemokine receptor profile, suggesting these cells are already activated in the periphery of IA patients, and are recruited and further activated into the joint of IA patients.

(19A157) ABSTRACT 42

REGULAR POSTER 34

**Awareness of Importance of Vaccination in Patients with Ankylosing Spondylitis(AS).**

**Author(s)**

Azhar Abbas, Paul Ryan, Gillian Fitzgerald, Gaye Cunnane, Richard Conway, Michelle Doran, Finbar O Shea

**Department(s)/Institutions**

Department of Rheumatology St.James Hospital Dublin

**Introduction**

Patients rheumatic diseases are at increased risk of dying from pulmonary infections<sup>1-3</sup>. EULAR strongly recommends inactivated influenza and pneumococcal vaccination for all patients with AIIRD<sup>4</sup>.

**Aims/Background**

To establish the awareness of, and attitude towards, vaccinations in a cohort of patients with a diagnosis of AS.

**Method**

15 questions were asked to patients attending an AS clinic in St.James Hospital over a 3 month period. Questions related to duration of AS diagnosis, current treatments, patient awareness and uptake of influenza and pneumococcal vaccinations, and respiratory illness and hospitalisation history since time of diagnosis with AS. Responses were compiled on a proforma.

**Results**

The average age of respondents was 48.4 years. At the time of survey, 46.67% patients were on a biologic agent. Only 3.33% was being treated with methotrexate in addition to a biologic agent.

A total of 83.33% and 46.66% had heard of the influenza vaccination and pneumococcal vaccine respectively, with only 63.33% being aware of where they could receive these vaccines. When asked if anyone had mentioned vaccination at any point during their treatment for AS, only 36.66%, with 43.33% reporting negatively and 20% unable to remember

Only 43.33% patients had received the influenza vaccine in the past year, and only 16.66% had received the pneumococcal vaccine in the past 5 years.

In terms of attitudes towards vaccination in general, 43.33% patients felt that vaccination was safe; 43.33% said they would get vaccinated on their doctor's advice; 6.66% said they would get vaccinated if their medical card or insurance covered the cost; 26.66% offered alternative responses or no response.

Since their diagnosis, 46.66% said that they had suffered infection(s). The most common infection reported was pneumonia (42.86%), flu (35.71%), shingles (21.43%), and other (35.71%). Only 2 patients reported that they were admitted to hospital with infections.

**Conclusions**

Awareness and uptake of vaccinations against influenza and pneumococcal pneumonia was poor amongst patients with AS in our hospital. The most common reason cited for lack of awareness and uptake of these vaccines was a lack of patient education by health care professionals. Attitudes towards vaccination were generally very positive.

1. Wolfe F, Mitchell DM, Sibley, et al

(19A160) ABSTRACT 43

REGULAR POSTER 35

**Safe Prescribing of Methotrexate – A Completed Audit Loop**

**Author(s)**

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**Department(s)/Institutions**

Dermatology Department, Our Lady of Lourdes Hospital Drogheda

**Introduction**

Methotrexate(MTX) is a potent immunosuppressant used in the treatment of a variety of rheumatological, dermatological and oncological conditions. MTX is a safe and efficacious drug if used correctly, however, incorrect prescribing, dispensing and use of methotrexate can result in significant patient morbidity and mortality due to severe adverse effects. In order to avoid errors the Pharmaceutical Society of Ireland (PSI) Guidelines recommend that methotrexate prescriptions should include 2.5mg dosing, number of



tablets, total dose and weekly intervals. Specifying the day of intake is also encouraged. Methotrexate should also always be prescribed in conjunction with folic acid.

#### **Aims/Background**

To retrospectively review prescriptions of methotrexate in our dermatology department.

#### **Method**

We audited MTX prescriptions from January 2016 - July 2018 according to the PSI guidelines. Two interventions were then implemented; 1) consultant led education on MTX prescribing errors, 2) Example of correctly prescribed methotrexate placed in clinic rooms. We then re-audited MTX prescriptions from July 2018 - December 2018 to complete the audit loop.

#### **Results**

120 MTX prescriptions were reviewed. 53 errors were identified on 34 prescriptions. 2 prescriptions did not include total dose. 20 prescriptions did not instruct 2.5mg tablets to be dispensed. 28 prescriptions did not outline number of tablets to be dispensed. One prescription did not include day of intake or weekly dosing. 3 prescriptions did not include a prescription for folic acid. Following the implementation of our 2 interventions a further 30 prescriptions were audited. Only 1 error was identified.

#### **Conclusions**

There was a significant reduction in prescribing errors of MTX, from 23% to 3%, following our intervention. This highlights the importance of focused senior-led education on high-risk error-prone areas of prescribing in conjunction with visual examples of correct prescribing.

#### **(19A162) ABSTRACT 44**

#### **REGULAR POSTER 36**

### **Inpatient consult requests to the rheumatology service of a tertiary hospital: a review**

#### **Author(s)**

Marianne Riordan, Geraldine M McCarthy

#### **Department(s)/Institutions**

Rheumatology Department, Mater Misericordiae University Hospital, Dublin

#### **Introduction**

With a growing aged population in Ireland, the prevalence of rheumatic and musculoskeletal disorders is expected to increase substantially. The continued auditing of rheumatology services is required to improve service provision and ensure adequate resource availability.

#### **Aims/Background**

The aim of this audit was to explore the nature and outcomes of inpatient rheumatology consult requests by medical teams.

#### **Method**

A retrospective review of inpatient consult requests to the rheumatology service was conducted between the 1st February and 30th April 2019. Referral data were accessed through the hospital's computer system and analysed using Microsoft Excel. Patient demographics, question from referrer, pre-existing rheumatological diagnosis, referral origin and priority, and repeat consults were extracted. Final diagnosis was determined by reviewing discharge letters.

#### **Results**

A total of 136 consults were requested on 124 inpatients. The average age was 65.09 years (range 22-96) and 66 were female (53%). 53 patients (42.7%) had existing rheumatological diagnoses. 48 consults (35.3%) were queries relating to existing diagnoses, including medication advice (n=23). Additional consults related to crystal arthropathies (n=27), vasculitis (n=24) (9 with existing diagnoses), rheumatoid arthritis/inflammatory arthritis (n=14),

osteoarthritis (n=11), connective tissue diseases (n=8) (5 existing diagnoses), polymyalgia-rheumatica (n=8), dermatomyositis (n=5) (2 existing diagnoses), seronegative arthropathies (n=3), SLE (n=2) and 'other' musculoskeletal issues (n=20), 2 were for pyrexia of unknown origin. 3 were for patients who missed rheumatology appointments due to inpatient admission.

Referrals originated from general medical teams (n=89), neurology/stroke (n=18), cardiothoracic surgeons (n=9), general surgeons (n=4), ENT (n=2), psychiatry (n=1) and orthopaedics (n=1). 16 (11.7%) were requested urgently and 12 repeat consults were requested. 36 patients (29%) were offered follow-up outpatient appointments and the rheumatology service took over care of 3 consults. 48 discharge letters (38.7%) did not document the rheumatology consult or final diagnosis.

#### **Conclusions**

A majority of referrals were for crystal arthropathy and medication advice for existing rheumatological diagnoses. The provision of further education, particularly with regards medication, might be useful for medical teams. Given the large proportion of discharge letters not mentioning patients' rheumatology consults, interns, who are largely responsible for discharge letters, might benefit from additional education on the importance of same.

#### **(19A166) ABSTRACT 45**

#### **REGULAR POSTER 37**

### **Divergent Roles of Rheumatoid Arthritis Synovial Dendritic Cells**

#### **Author(s)**

Mary Canavan 1, Viviana Marzalioli 1, Vipul Bhargava 2, Ronan Mullan 3, Douglas J Veale 4, Ursula Fearon 1

#### **Department(s)/Institutions**

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#### **Introduction**

Dendritic Cells (DC) are potent antigen presenting cells which can be subdivided into CD141 and CD1c DC. We reported a previously unacknowledged role of CD141 + DC in the RA synovium however, the identification and function of CD1c + in RA has yet to be fully elucidated.

#### **Aims/Background**

To investigate if CD1c + DC are present in the RA synovium and if they are transcriptionally and functionally distinct to synovial CD141 + DC.

#### **Method**

Synovial biopsies were obtained via arthroscopy and enzymatically and mechanically dissociated to yield a single cell suspension. Synovial fluid mononuclear cells (SFMC) and peripheral blood mononuclear cells (PBMC) in addition to synovial tissue digests were stained with a panel of fluorochrome conjugated antibodies and analysed by multicolour flow cytometry. CD1c + DC and CD141 + DC were magnetically sorted from RA synovial fluid and cocultured with allogeneic CTV labelled T cells. Finally, RNA sequencing was performed on sorted synovial CD1c and CD141 DC and downstream bioinformatic analysis was performed.

#### **Results**

A distinct population of CD1c+ DC were identified in the RA synovium with high expression of DC maturation markers CD80 and CD40. CD1c + DC express high levels of the chemokine receptors CCR7 and CXCR4 suggestive of increased migration of DC to the joint. Furthermore, upon examination of peripheral blood and synovial fluid CD1c + DC, we demonstrate increased frequencies

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Administer after i.v. infusion of the glucocorticoid component. **Chronic lymphocytic leukaemia (CLL):** in combination with chemotherapy, for previously untreated and relapsed/refractory CLL: 375 mg/m<sup>2</sup> BSA, on day 0 of the first treatment cycle, followed by 500 mg/m<sup>2</sup> BSA on day 1 of subsequent cycles for 6 cycles in total. Prophylactic hydration and uricosatics recommended 48 hours prior to **Truxima**. Where lymphocyte counts >25x10<sup>9</sup>/L, administration of prednisone/prednisolone 100mg i.v. shortly before **Truxima** is recommended. **Rheumatoid arthritis (RA):** in combination with methotrexate (MTX), for adults with severe active RA who have had an inadequate response or intolerance to other DMARDs including one or more TNF inhibitor therapies. 1000mg i.v. infusion followed by a second 1000 mg i.v. infusion two weeks later. Evaluate need for further courses after 24 weeks (see SPC). Pre-medication with i.v. 100 mg methylprednisolone should be given 30 minutes prior to each infusion. **Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA):** in combination with glucocorticoids, for treatment of adult patients with severe, active GPA (Wegener's) and MPA: for the induction of remission: 375 mg/m<sup>2</sup> BSA once weekly for 4 weeks. As maintenance treatment: 500mg i.v. infusion followed by a second 500mg i.v. infusion 2 weeks later, followed by a 500mg i.v. infusion every 6 months after, for at least 24 months from remission or up to 5 years with higher risk of relapse. Pre-medication with i.v. 100 mg methylprednisolone should be given 30 minutes prior to each infusion for patients in disease remission. Pneumocystis jirovecii pneumonia (PCP) prophylaxis recommended during and following **Truxima** treatment. **Pemphigus vulgaris (PV):** in patients with moderate to severe PV: 1000mg i.v. infusion followed by a second 1000mg i.v. infusion 2 weeks later. A maintenance infusion of 500mg i.v. should be administered at 12 and 18 months and then every 6 months after if needed. In case of relapse, give 1000mg i.v. Give subsequent infusions at least 16 weeks following previous infusion. Pre-medication with i.v. 100 mg methylprednisolone should be given 30 minutes prior to each infusion. Pneumocystis jirovecii pneumonia (PCP) prophylaxis recommended during and following **Truxima** treatment. **All indications:** No dose reductions of **Truxima** are recommended. Standard dose reductions for any concomitant chemotherapeutic medicinal product should be applied. **Administration:** Give RA, GPA/MPA and PV patients the patient alert card with each infusion. Administer prepared **Truxima** as an i.v. infusion, through a dedicated line, with full resuscitation facilities immediately available, under the supervision of an experienced healthcare professional. Do not administer as an i.v. push or bolus. Administer anti-pyretic and an antihistaminic before each infusion. Consider glucocorticoid (GCC) premedication if **Truxima** is not given with GCC-containing chemotherapy. Monitor closely for onset or evidence of cytokine release syndrome (CRS). Interrupt infusion immediately if evidence of a severe reaction (e.g. severe dyspnoea, bronchospasm or hypoxia). Evaluate NHL patients for tumour lysis syndrome (TLS). First infusion: Recommended initial rate of 50 mg/h for the first 30 minutes, which can then be escalated in increments of 50 mg/h every 30 minutes up to 400 mg/h. Subsequent infusions: Recommended initial rate of 100 mg/h and increased by 100 mg/h increments every 30 minutes, up to 400 mg/h. Alternative faster infusion schedule in RA only (4mg/mL in 250mL infusion volume): if no serious infusion related reaction (IRR) during first or subsequent infusions at standard rates (above), initiate at 250 mg/h for the first 30 minutes and escalate to 600 mg/h over 90 minutes. Faster infusion not suitable for patients who have clinically significant cardiovascular disease, arrhythmias or previous serious IRR to biologic therapy or rituximab. **Contraindications:** Hypersensitivity to the active substance, severely immunocompromised patients. Active severe failure (NYHA class III/IV) or severe, uncontrolled cardiac disease in patients with RA, GPA/MPA or PV. **Precautions and warnings:** To improve the traceability of biological medicinal products, the trade mark and the batch number of the administered product should be recorded in the patient file.

Contains 2.3 mmol sodium per 10mL vial and 11.5 mmol sodium per 50mL vial – take into consideration for patients on a controlled sodium diet. **Progressive multifocal leukoencephalopathy (PML):** Very rare cases of fatal PML have been reported. Monitor patients for new or worsening neurological symptoms suggestive of PML and suspend until PML excluded. Permanently discontinue if confirmed. See SPC for further information. **Infusion related reactions (IRRs):** Rituximab is associated with IRRs, including CRS, TLS, anaphylactic and hypersensitivity reactions, including severe reactions with fatal outcome. Severe IRRs are characterised by pulmonary events and may include features of tumour lysis or rapid TLS in addition to reactions such as fever, chills, rigors, hypotension, urticaria and angioedema. Use extreme caution and closely monitor first infusion when treating patients with >25x10<sup>9</sup>/L circulating malignant cells or high tumour burden (higher risk of severe CRS). Consider reduced infusion rate or split dosing where lymphocyte counts >25x10<sup>9</sup>/L. See SPC for further details on severe IRRs. IRRs of all kinds have been observed in 77% of patients treated with rituximab. Common IRRs are generally reversible with a reduction in rate, or interruption, of rituximab infusion and administration of an antipyretic, an antihistaminic and occasionally, oxygen, i.v. saline or bronchodilators. Temporary or permanent discontinuation may be necessary if severe or if the same adverse events recur a second time. In most cases the infusion can be resumed at a 50% reduction in rate when symptoms have completely resolved. Anaphylaxis and other hypersensitivity reactions have been reported following i.v. administration of proteins to patients. IRRs may also be associated with myocardial infarction, atrial fibrillation, pulmonary oedema and acute reversible thrombocytopenia. Consider withholding antihypertensives for 12 hours prior to infusion due to risk of hypotension. Treat with caution and closely monitor patients with a history of pulmonary insufficiency or pulmonary tumour infiltration. **Cardiac disorders:** Closely monitor patients with a history of cardiac disease and/or cardiac chemotherapy. **Infections:** Patients are at an increased risk of developing infections, including serious infections with fatal outcome. Do not administer if active and/or severe infection present or if severely immunocompromised. Caution in patients with a history of, or susceptibility to recurring/chronic infections. Determining immunoglobulin levels in RA, GPA/MPA and PV before treatment is recommended. Hepatitis B (HBV) reactivation has been reported, including cases with a fatal outcome. HBV screening should be performed before initiation of **Truxima**. Patients with active hepatitis B disease should not be treated. Patients with positive serology for HBV should consult liver specialists and be monitored and managed to prevent reactivation. **Haematological toxicities:** Caution in patients with neutrophil counts <1.5 x 10<sup>9</sup>/L and/or platelet counts <75 x 10<sup>9</sup>/L as clinical experience in this population is limited. Perform regular blood counts during **Truxima** therapy in all indications, and prior to each course and regularly up to 6-months after cessation of treatment in RA, GPA/MPA and PV. **Immunisations:** Live viral vaccines are not recommended. Response to non-live vaccinations may be reduced. See SPC for further information. **Skin reactions:** Severe skin reactions such as Toxic Epidermal Necrolysis (TEM) and Stevens-Johnson Syndrome (SJS), including fatal outcomes, have been reported - permanently discontinue treatment. **Malignancy:** The possible risk for the development of solid tumours with the use of immunomodulatory drugs cannot be excluded. **Concomitant/sequential use of other DMARDs in RA:** The concomitant use of **Truxima** and anti-rheumatic therapies other than those specified for RA is not recommended. Monitor patients for signs of infection if biologic agents and/or DMARDs are used following **Truxima** therapy. **Interactions:** Limited data are available (see SPC). Patients with human anti-mouse antibody or anti-drug antibody titres may have allergic or hypersensitivity reactions when treated with other diagnostic or therapeutic monoclonal antibodies. **Fertility, pregnancy and lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 12 months after **Truxima** treatment. **Truxima** should not be administered during pregnancy. Do not breast-feed in the 12 months following treatment. **Side effects:** **Very common (≥ 1/10) and common (≥ 1/100, < 1/10) side effects:** Viral infection, bacterial infection, bronchitis, acute bronchitis, sepsis, pneumonia, febrile infection, herpes zoster, respiratory tract infections, fungal infection, sinusitis, hepatitis B, infections of unknown aetiology, neutropenia/febrile neutropenia, leucopenia, thrombocytopenia, anaemia, pancytopenia, granulocytopenia, infusion related reaction (hypertension, nausea, rash, pyrexia, pruritus, urticaria, throat infection, hot flush, hypotension, rhinitis, rigors, tachycardia, fatigue, oropharyngeal pain, peripheral oedema, erythema), angioedema, hypersensitivity, hyperglycaemia, weight decrease, face oedema, increased LDH, hypocalcaemia, paraesthesia,

hypoesthesia, insomnia, vasodilatation, dizziness, anxiety, agitation, lacrimation disorder, conjunctivitis, tinnitus, ear pain, myocardial infarction/myocardial arrhythmia, atrial fibrillation, cardiac disorder, orthostatic hypotension, bronchospasm, respiratory disease, chest pain, dyspnoea, cough/increased cough, vomiting, diarrhoea, abdominal pain, dysphagia, stomatitis, constipation, dyspepsia, anorexia, throat irritation, alopecia, sweating/night sweats, skin disorder, hypertonia, myalgia, back pain, neck pain, pain, fever, chills, asthenia, headache, tumour pain, flushing, malaise, cold syndrome, shivering, multi-organ failure, decreased IgG levels, urinary tract infection, gastroenteritis, tinea pedis, hypercholesterolemia, migraine, sciatica, depression, oesophageal reflux, mouth ulceration, arthralgia/musculoskeletal pain, muscle spasms, muscle weakness, osteoarthritis, bursitis, decreased IgM levels. Additional side effects in ≥ 5% GPA/MPA patients in clinical trials: Nasopharyngitis, cytokine release syndrome, hyperkalaemia, tremor, acne, epistaxis, nasal congestion, pain in extremities, decreased haemoglobin, influenza-like illness. Additional side effects in ≥ 5% PV patients in clinical trials: persistent depressive disorder, irritability, oral herpes, fatigue, tachycardia, skin papilloma. **Uncommon (< 1/100) but potentially serious, including fatal, side-effects:** Serious viral infection, pneumocystis jirovecii, progressive multifocal leukoencephalopathy, reactivation of hepatitis B, infusion related reactions (generalised oedema, bronchospasm, wheezing, laryngeal oedema, angioneurotic oedema, generalised pruritus, anaphylaxis, anaphylactoid reaction), tumour lysis syndrome, cytokine release syndrome, serum sickness, coagulation disorders, aplastic anaemia, haemolytic anaemia, late neutropenia, depression, peripheral neuropathy, cranial neuropathy, severe vision loss, facial nerve palsy, loss of other senses, left ventricular failure, supra-ventricular tachycardia, ventricular tachycardia, angina/angina pectoris, heart failure, atrial flutter, atrial fibrillation, myocardial ischaemia, bradycardia, severe cardiac disorders, vasculitis, leukocytoclastic vasculitis, asthma, bronchiolitis obliterans, hypoxia, respiratory failure, pulmonary infiltrates, interstitial lung disease, gastrointestinal perforation, Stevens-Johnson syndrome, toxic epidermal necrolysis, renal failure. Cases of posterior reversible encephalopathy syndrome (PRES) / reversible posterior leukoencephalopathy syndrome (RPLS) have been reported. Please refer to the SPC for further information and a full list of side effects. **Overdose:** Intravenous doses of up to 5000 mg have been administered in a dose escalation study in CLL patients, which did not identify any safety signals. The infusion should be interrupted immediately and patient monitored closely, if overdose is experienced. **Legal category:** POM. **Presentations:** 100mg (pack of 2 vials), 500mg (1 vial). **Marketing Authorisation numbers:** EU/1/16/1167/001-2. **Marketing Authorisation holder:** Celtrion Healthcare Hungary Kft, 1062 Budapest, Váci út 1-3, WestEnd Office Building B torony, Hungary. Further information is available from Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandford Industrial Estate, Dublin 18, Ireland. For medical information enquiries, please contact medicalinformation@mundipharma.ie. **PI Code UK/TRU-17025(2) Date of Preparation July 2019.**

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of CD1c + DC in the synovium compared to peripheral blood. Synovial CD1c + DC are transcriptionally distinct from synovial CD141 + DC as identified by Principal component analysis (PCA) and hierarchical clustering analysis. Moreover, IPA analysis revealed that pathways involved in T cell activation, T cell exhaustion and DC maturation were upregulated in synovial CD1c + DC compared to CD141 + DC. Following coculture of allogeneic T cells with either synovial CD1c + DC or CD141 + DC we noted a preferential induction of CD4 + T cell derived GM-CSF, TNF $\alpha$  and IFN $\gamma$  in CD1c + DC cocultures. However, CD141 + DC were superior in induction of a TNF $\alpha$  producing CD8 + T cell population.

#### Conclusions

Mature CD1c DC are enriched in the RA joint and are transcriptionally distinct from synovial CD141+DC. Synovial DC may play distinct roles in RA pathology via differential T cell activation.

#### (19A170) ABSTRACT 46

#### REGULAR POSTER 38

### UK and Ireland Paediatric and Young Person Primary Sjögren Syndrome Cohort Study and Repository (UK/Ireland PpSS cohort study and repository)

#### Author(s)

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#### Department(s)/Institutions

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#### Introduction

Sjögren syndrome, a chronic multisystem autoimmune disease is characterised by inflammation of the exocrine glands, principally the salivary and lacrimal glands. It can present with more extensive exocrinopathy as well as extra-glandular, systemic features.

Incidence and prevalence rates of primary SS (pSS) vary. Juvenile-onset-pSS is believed to be rare; however it is likely that it is under-recognised and therefore under-diagnosed. To date there have been no studies reporting accurate incidence or prevalence of paediatric pSS (PpSS).

Diagnosing pSS can be challenging. Many of the cardinal symptoms are non-specific and no gold standard biomarker of disease exists. Between 1965–2002 eleven diagnostic criteria sets were developed, none of which have gained universal acceptance or been validated for use in a paediatric population. Until recently, the most widely used criteria were those developed by the American-European Consensus Group.

It remains well recognised that international consensus on classification is important for standardisation, particularly in relation to research and monitoring treatment outcomes. With this in mind, the 2016 ACR/EULAR criteria were developed. However, there still remains a paucity of validated classification criteria for diagnosing PpSS. Paediatric-focussed criteria are required as features of PpSS differ from those observed in adults. Applying adult criteria to a paediatric population may lead to mis- and/or under-diagnosis.

#### Aims/Background

Identify epidemiological, clinical and laboratory characteristics of PpSS in a multi-centre cohort.

Develop universally accepted classification criteria validated for use in a paediatric population.

#### Method

Inclusion criterion for entry into the UK/Ireland PpSS cohort study and repository is a diagnosis of pSS made before 18-years. A data collection pack will be sent to willing author-participants. Demographic, clinical and laboratory/histological data at diagnosis and subsequent follow-up appointments will be collected. Biological-samples including blood, tears, saliva, urine, glandular and extra-

glandular (e.g. renal) tissue will be collected prospectively if available. Outcome measures related to disease-activity and damage, as well as patient-reported outcomes will also be collected.

#### Conclusions

The UK/Ireland PpSS cohort study and repository will provide a powerful resource to help improve our understanding of this rare disease.

#### (19A172) ABSTRACT 47

#### REGULAR POSTER 39

### An Evaluation of Polypharmacy and Adverse Drug Events in Older Adults with Rheumatic Disease

#### Author(s)

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#### Department(s)/Institutions

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Department of Rheumatology, Cork University Hospital, Cork, Ireland

#### Introduction

Polypharmacy among older adults is a well-documented problem. The practice has been associated with potentially inappropriate medications (PIMs), adverse drug events (ADEs) and hospitalization. The Screening Tool of Older Persons' Medications (STOPP) criteria has never been used to evaluate polypharmacy in a rheumatic disease population.

#### Aims/Background

This retrospective cohort study aims to evaluate polypharmacy, ADEs and anticholinergic burden in the  $\geq 65$  population with rheumatic disease.

#### Method

All patients  $\geq 65$  with a diagnosed rheumatic disease were included in this study. Patients' medication lists, specific rheumatic disease, laboratory findings and associated comorbidities were obtained from their medical charts at rheumatology outpatient clinics. The data was screened for PIMs using the STOPP criteria and probable ADEs using the WHO-UMC criteria. Anticholinergic burden was determined using the ACB calculator. Polypharmacy in this project was defined  $\geq 4$  regular prescription medications.

#### Results

70 patients were studied. The prevalence of polypharmacy was 94%. The median (IQR) number of regular prescription medications was 7 (2-16). PIMs were recorded in 43 patients (61%). Increasing numbers of medications was a significant risk factor for PIMs ( $p=0.0027$ ). ADEs were detected in 18 patients (26%). The ADE detection rate in PIM positive patients was 35% (15/43) and 11% (3/27) in PIM negative patients. A patient who was PIM positive had a statistically significant risk of having an ADE ( $p=0.047$ ). Of the ADEs detected, 73% were due to a STOPP PIM.

Increasing numbers of medications was a significant risk factor for an increased anticholinergic burden ( $p=0.017$ ). An anticholinergic burden of  $\geq 3$  was a statistically significant risk factor for falls ( $p=0.025$ ), however it was not a statistically significant risk factor for cognitive decline ( $p=0.073$ ).

#### Conclusions

There is a high prevalence of polypharmacy in older adults with rheumatic disease. Increasing numbers of medications is statistically associated with increased numbers of PIMs, ADEs and increased anticholinergic burden. An anticholinergic burden of  $\geq 3$  is associated with an increased risk of falls.

The STOPP criteria offer an effective method of detecting the presence of and reducing inappropriate prescribing. Evaluation of polypharmacy using the STOPP criteria may lead to a reduction of ADEs in older adults with rheumatic disease.



(19A174) ABSTRACT 48

REGULAR POSTER 40

**Patient Satisfaction with Biosimilar Therapy Initiation and Switching.**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

From June 1 to July 19 2019, 106 patients attending TUH rheumatology department who were prescribed etanercept or adalimumab were initiated on best value biosimilar or switched to best value biosimilar from bio-originator. We performed a call back from our Rheumatology helpline to follow up these patients and their initial experience of initiation or switching to biosimilar therapy.

**Aims/Background**

To follow up the patients and their initial experience of initiation or switching to biosimilar therapy.

**Method**

A standard introduction explaining the reason for call back and a standardised set of questions were used with each patient (appendix 1). If patients declined to provide information they were thanked for taking the call. We set an initial target of the first 50 telephone respondents as a representative sample.

**Results**

46 patients were contacted by phone. No patient declined to participate. Indications for biologic therapy were Rheumatoid Arthritis = 23, Psoriatic arthritis = 10, AS = 7, Other = 8. The following therapies were prescribed:- Benepali = 29, Imraldi 13, Hulio = 0, Amgevita = 4. 28 (61%) of 46 patients had commenced biosimilar therapy. Of the 18 who had not yet commenced therapy, 10 still had supply of bio-originator, 1 was awaiting results of screening tests, 3 had not had time to get their prescription and 4 listed other reasons. When asked if it the biosimilar therapy was available on presentation of prescription 2 reported same day dispensing and 16 received it the next day while 10 received it more than one day later. The average number of weeks of self-administration of biosimilar was 2 weeks at the time of telephone contact (range 0-6). 24/28 (86%) were satisfied with the injection device/process, 4 reported dissatisfaction with the injection device/process. 24/28 (86%) were satisfied with switching, 3 were dissatisfied and 1 did not respond.

**Conclusions**

86% of patients initiated or switched to biosimilar therapy reported initial satisfaction with the therapy, the delivery device and the switching / initiation process. We are going to monitor longer term satisfaction and examine the areas of dissatisfaction identified to improve our initiation/switching process.

(19A179) ABSTRACT 49

REGULAR POSTER 41

**A Study of Abatacept Retention in a Tertiary Referral Centre**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

Abatacept is a T-cell co-stimulation blocker licensed for use in rheumatoid arthritis. It improves symptoms, reduces disease activity and slows radiographic progression.

**Aims/Background**

We present data on abatacept drug retention in our patients.

**Method**

We performed a retrospective chart review of all patients treated with abatacept in our hospital since 2010. We gathered data on patient demographics, duration of treatment with abatacept, adverse events and DMARD combinations used with abatacept.

**Results**

113 patients were treated with abatacept. 93 (82.3%) had rheumatoid arthritis, 14 (12.4%) has a spondyloarthritis, 5 (4.4%) had juvenile idiopathic arthritis and 1 (0.9%) had CPPD-related arthritis.

Of 113 patients, 50 (44.2%) remain on treatment. Of those who had treatment discontinued, 23 (20.4%) had primary failure, 16 (14.2%) had secondary failure and 18 (15.9%) had treatment discontinued due to adverse events.

Of DMARDs used prior to abatacept, 73 (64.6%) patients had methotrexate (MTX), 30 (26.5%) had leflunomide (LEF), 30 (26.5%) had sulfasalazine (SLZ), and 81 (71.7%) had a prior tumour necrosis factor inhibitors (TNFi).

49 patients (43.4%) were co-prescribed DMARDs in combination with abatacept as follows: glucocorticoids in 15 (13.3%) patients, MTX in 38 (33.6%), LEF in 11 (9.7%), Hydroxychloroquine in 7 (6.2%) and SLZ in 6 (5.3%).

Serious infections were observed in 25 (22.1%) patients, cardiovascular events in 1 (0.9%) patient, injection site reactions in 1 (<1%) patient and other mucocutaneous adverse events in 12 (10.6%).

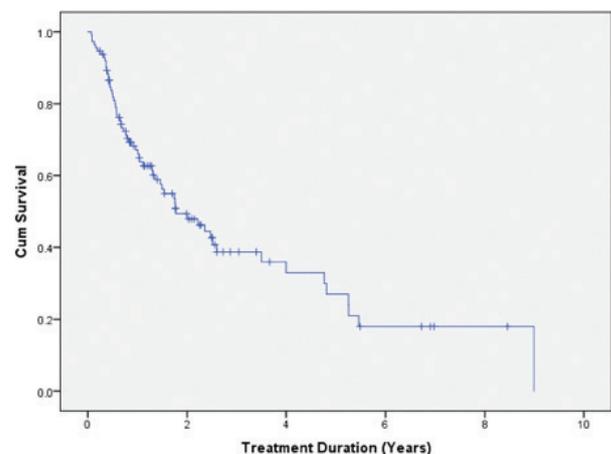
After abatacept discontinuation, 14 patients (12.4%) were switched to a synthetic DMARD, 14 (12.4%) were switched to a TNFi, 11 (9.7%) were switched to an IL-6 inhibitor, 8 (7.1%) were switched to a janus kinase inhibitor (JAKi), and 10 (8.6%) were switched to other biologic DMARDs. 31 (27.4%) achieved disease control on their new DMARD. Data on disease control post switch was unavailable in 43 (38.1%) patients.

Abatacept achieved a clinical response in 78 (69%) patients. Median retention of abatacept in years was 1.77 (95% CI 1.0-2.5).

**Conclusions**

Nearly half of patients commenced on abatacept in our center remain on the drug and nearly 2/3 of all patients treated achieved a meaningful clinical response. Median retention of abatacept was 1.77 years.

Figure





Figure

<b>Abatacept responders</b>	<b>78 (69%)</b>
<b>Median Abatacept retention</b>	<b>1.77years (95%CI 1.0-2.5)</b>
<b>No. still on Abatacept</b>	<b>50 (44.2%)</b>
<b>No. serious infections</b>	<b>25 (22.1%)</b>
<b>Disease control on DMARD post switch</b>	<b>31 (27.4%)</b>

(19A182) ABSTRACT 50

REGULAR POSTER 42

**Seroreversion For Rheumatoid Factor is common in those with RA on Biologic Therapy**

**Author(s)**

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**Department(s)/Institutions**

C Connolly Hospital, Blanchardstown and RCSI

**Introduction**

Serology findings in RA have been reported as stable over time. Rheumatoid factor (RF) remains an important tool in the diagnosis of rheumatoid arthritis. It has been reported that serology for RF is stable over time, and that titres are weakly associated with disease activity.

**Aims/Background**

While the stability of various autoantibodies involved in rheumatoid arthritis have been reported, little has been done thus far to investigate what factors influence seroreversion. We interrogated the rates, and the likely factors that might determine seroreversion.

**Method**

Of 89 consecutive rheumatoid arthritis (RA) patients attending clinic, 26 had RF checked on more than one occasion. We compared baseline and the most recently updated serology for RF, in patients with a clinical diagnosis of rheumatoid arthritis, and examined for inconsistency, contingent upon treatment strategies, smoking status, follow-up disease activity, and RF titre.

**Results**

Seroreversion was observed in a large number of subjects 6/19 (31.6%). Having ever smoked was associated with lower seroreversion rates than non-smokers ( $p=0.04$ ), and those with an initial moderate or low RF titre were more likely to serorevert ( $p=0.04$ ). No differences were observed between those who seroreverted and those who did not in respect of age of onset, disease activity (by DAS28-CRP or ESR), disease duration, or time between initial RF test and the most recent. While not statistically significant ( $p=0.1$ ) all those who seroreverted were all receiving biologic therapy.

**Conclusions**

We report regular seroreversion for RF in those on biologic therapies who have never smoked. More data is needed to better understand how modern treatments influence disease progression and outcome in RA.

(19A185) ABSTRACT 51

REGULAR POSTER 43

**Clinical Audit of Tuberculosis Prescreening, Latent TB identification and Treatment prior to Biologic Commencement**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

The advent of biologics has revolutionized the management of chronic inflammatory disease. However, these therapies are not without potential risk including the risk of infection in particular the possible development of Tuberculosis.

Screening of latent TB infection (LTBI) is thus necessary prior to their initiation.

**Aims/Background**

The aims of this study were to assess our compliance with screening recommendations prior to the initiation of biologics in our institution. We also wished to identify the prevalence of LTBI among this patient cohort and assess the number of these patients who underwent preventative treatment and rescreening.

**Method**

An audit was conducted over a one month period in December 2018. A retrospective database containing patients commenced on a biologic was utilized to identify the patient cohort. Clinic letters were then used to analyze the documentation of Chest X-ray (CXR) and Tuberculin Skin Test (TST)/ Interferon Gamma Release Assay (IGRA) performed as a prescreen.

They were also used to identify the cases in which LTBI was found and the documented number of cases treated for LTBI. We also audited the number of cases rescreened following treatment and an initial positive screen.

**Results**

A total of 643 people were identified.

Of those 635 (99%) had documentation of CXR performed.

605 (94%) had documentation of IGRA/TST.

The diagnosis of LTBI was established in 86 (13%).

Of those documented to have LTBI, 14 (16%) failed to have documentation of preventative treatment.

65 (76%) had documentation of rescreening post treatment.

Of interest 11 (17%) of those rescreened had a persistent positive test.

**Conclusions**

Our documentation of compliance with pre screening was high, however there remains room for improvement. Our rate of rescreening also falls below desired standards.

We intend to hold a teaching session for all members of the rheumatology department and re-audit post same.



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(19A192) ABSTRACT 52

REGULAR POSTER 44

**Outcomes And Processes Of Psychological Flexibility During Acceptance And Commitment Therapy (ACT), Group Based Treatment For Patients With Chronic Pain In A Rheumatology Context**

**Author(s)**

Nóirín Lennox, Prof Siobhán O'Neill<sup>1</sup>, Prof Ailish Hannigan<sup>2</sup>, Helen Rooney<sup>3</sup>, Dr Alexander Fraser<sup>2, 3</sup> and Dr Joseph Devlin<sup>3</sup>

**Department(s)/Institutions**

1. Department of Psychology Ulster University, 2. Graduate Entry Medical School, University of Limerick, 3. Rheumatology Services Croom, University Hospital Limerick.

**Introduction**

ACT (pronounced as one word) is a type of Cognitive Behavioural Therapy that promotes a therapeutic process known as "Psychological Flexibility". A key feature of this therapy in the context of chronic pain is that it focuses on behaviour change rather than symptom reduction only.

**Aims**

This was a prospective study, which aimed to design, implement and evaluate ACT based, group, interdisciplinary, rehabilitation programmes for people with chronic pain attending rheumatology services. Specifically it aimed to conduct an outcome evaluation of 10 ACT and exercise programmes and to examine the mechanisms of its impact.

**Methods**

Data was collected at three time points; at assessment, on the last day of the interventions and at a 6-month review date following completion of the programme. Four self-report measures and two objective measures were used for the primary outcomes. To examine the processes of psychological flexibility, a further four validated measures were included at each time point. Paired t-tests and repeated measures ANOVA were used to test differences between time points.

**Results**

Results showed statistically significant improvements across all the primary outcome measures except for pain. Improvements made during the eight-week programmes were maintained at follow up for all the measures. In addition statistically significant improvements were made in all four process measures and these were maintained at follow up.

**Conclusions**

To the authors knowledge these are the first trials, examining ACT for chronic pain in a rheumatology context only. As such they add to the existing evidence for the effectiveness of Acceptance and Commitment Therapy for chronic pain.

(19A101) ABSTRACT 53

CASE POSTER 45

**Polyethylene Glycol (PEG) Causing Anaphylaxis: An Under-Recognised Excipient In Certolizumab Pegol And Movicol**

**Author(s)**

Eva McCabe<sup>1</sup>, Vincent Tormey<sup>2</sup>, John Paul Doran<sup>1</sup>

**Department(s)/Institutions**

1. Department of Rheumatology, University Hospital Galway 2. Department of Immunology, University Hospital Galway

**Introduction**

Certolizumab pegol (Cimzia) is the only pegylated Fc free anti-TNF monoclonal antibody currently available. Pegylation of biological proteins is when proteins and polyethylene glycol (PEG) undergo covalent conjugation resulting in increased drug stability. Macrologol is the international non-proprietary name for PEG. There have been

several reports of macrologol-induced hypersensitivity reactions but this is the first report of macrologol anaphylaxis associated with certolizumab pegol.

**Results**

A 37-year lady was commenced on certolizumab for psoriatic arthritis that was refractory to etanercept and ustekinumab in combination with methotrexate. She had some success previously with phototherapy in managing her skin disease. She also had a history of allergic rhinitis and a documented anaphylactic reaction to Movicol and carried an Anapen. Upon returning home, she injected the first dose of certolizumab. Ten minutes later, she noticed an injection-site reaction before developing generalised urticaria, dyspnoea, wheeze and presyncope. Her sister administered her Anapen and she was transferred to her local emergency department. On review, she tachycardic and hypotensive but physical examination was otherwise normal. Blood results showed an elevated WCC (22.4), lactate (7.1) but all other results including serum tryptase were normal.

On further questioning of her allergic history, she revealed that she had experienced a similar reaction to Movicol (PED 3350) two years prior and was prescribed an Anapen. Following liaison with immunology, it was felt that the likely culprit for her hypersensitivity reactions was the macrologol present in both medications. This was confirmed on skin-prick testing for allergens. Repeat serum tryptase was normal, out-ruling mastocytosis. She was started on adalimumab following negative skin-prick testing and tolerated this well with good symptom control.

**Conclusions**

The management of macrologol allergies is challenging as they are widely used in industry (medications, cosmetics and detergents) and may be present in medications used to treat reactions e.g. anti-histamines and steroids. The learning points here are that enquiring about previous allergic reactions is vital, reporting of adverse drug reactions to drug manufacturers are clinicians' ethical responsibility and patients with previous anaphylactic reactions should be encouraged to carry an in-date adrenaline pen on their person and wear a Medic Alert bracelet.

(19A108) ABSTRACT 54

CASE POSTER 46

**Rheumatoid arthritis presented as neck and skull bones erosions**

**Author(s)**

Khizer Iqbal, Sarah Quidawi, Carl Orr, Trevor Duffy

**Department(s)/Institutions**

Rheumatology Department, Connolly Hospital, Dublin 15

**Introduction**

Rheumatoid arthritis is a chronic systemic inflammatory disease. The environmental triggers in genetically susceptible patients causes synovial hypertrophy and chronic joint inflammation along with the potential for extra-articular manifestations.

**Aims/Background**

68 year old gentleman, smoker, frequent drinker presented with frequent falls without having significant medical history. He denied fatigue, weight loss, joints pains, Reynaud's phenomenon, hair thinning, skin changes, dryness of eyes and mouths. CT brain was nil acute with generalised cerebral and cerebellar changes advocated further imaging MRI brain. Interestingly, MRI showed the microvascular change in the brain with odontoid peg is eroded and considering last findings MRI cervical spine was being performed which demonstrated minor pannus at the atlantodental interval with some osseous erosion and mild marrow oedema. Multilevel spondylotic change in the cervical spine. To rule the cause of erosive arthropathy Rheumatoid factor, anti CCP, serum uric acid



and connective tissue disease screen was performed. Subsequently, Rheumatoid factor was 147IU/ml (0-19IU/ml), Anti CCP, CTD screen negative, CRP was 15.12 and serum urate is 215.

In the summary, we are left with the evidence of erosive disease, along with some evidence of inflammation of atlantoaxial junction with slightly raised CRP and strongly positive rheumatoid factors lead to opinion about the certainty of Rheumatoid arthritis and this is highly unusual presentation and wouldn't meet the classification criteria .Patient was commenced on disease modifying agent. Plain film radiographs of cervical spine on flexion and extension was performed to check the stability of cervical spine which was normal. Patient is on regular follow up list under Rheumatological services.

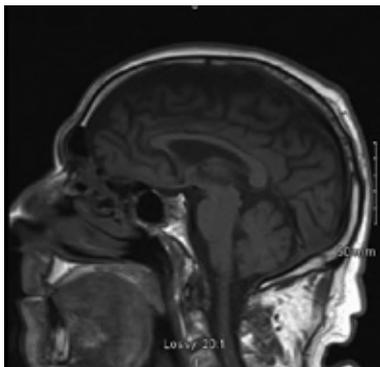
**Method**

A case report

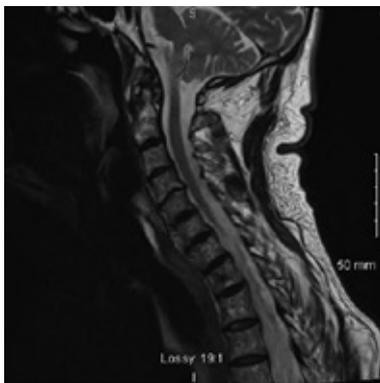
**Conclusions**

The incidence of asymptomatic cervical involvement in RA is high with reports of 33 to 50% of patients having no symptoms, and thus heightened awareness of the frequency of cervical involvement is paramount in the early detection of the beginning stages of the disease even in the absence of symptoms. It is crucial not to miss signs of myelopathy given the increased morbidity and mortality associated with the onset of neurologic deficit in patients with RA.

Figure



Figure



**(19A109) ABSTRACT 55**

**CASE POSTER 47**

**Even the hardest puzzles have the solutions: Recurrent Encapsulated bacteraemia as presentation of systemic lupus erythematosus**

**Author(s)**

Khizer Iqbal, Fahd Adeeb, Muhammad Haroon

**Department(s)/Institutions**

Rheumatology Department, University Hospital Kerry

**Introduction**

We are reporting the case about the critical encapsulated bacteraemia in the young female patient on two different occasions found to be underlying low complements levels secondary to systemic lupus erythematosus as presentations

**Aims/Background**

A 17 year old lady with no medical history presented with headache associated with photo phobia and generalized purpuric rash and unexplained weight loss. Investigations revealed positive meningococcal antigen on LP. By considering her weight loss history CT TAP was done revealed diffuse bronchial thickening and general lymphadenopathy . She was treated with antibiotics as per protocol and discharged .After a month she was presented again with septic shock in the hospital with very raised inflammatory markers .Subsequently Blood cultures showed streptococcus pneumoniae . CT thorax showed focal consolidation and with bilateral effusion. Again she was treated with antibiotics as per local guidelines. During her stay in ITU she developed genital ulcers ,multiple drug reactions leading us to think about underlying connective tissue disorder .On further investigations she had hypocomplementinemia and strongly positive ANA ,anti Ro and anti U1RNP and anti smith leading to the diagnosis of lupus .

Patient was started on immunosuppressive therapy along with vaccination and patients didnt develop any other encapsulated infections and she is under the regular follow up in the rheumatology service .

**Method**

A case report

**Conclusions**

Timely diagnosis and treatment of the connective tissue disorders prevent the complications associated with high mortality and morbidity .A few cases of lethal infections secondary to low complements levels leading to the underlying connective tissue disorders had been reported .

It is important to think about connective tissue disorder if patients present with capsular microorganisms infections

In the future it is important to establish between the role of timely vaccinations encapsulated organisms and its effects on the prevention of these infections in patients with connective tissue disorders.

Figure



Figure



(19A121) ABSTRACT 56

CASE POSTER 48

**Case of Atypical Cutaneous Mycobacterium Chelonae Infection in Patient of Systemic Lupus Erythematosus After Cyclophosphamide Therapy**

**Author(s)**

Dr Sheraz Rasool, Dr Amr Affi, Dr Denise De Lord.

**Department(s)/Institutions**

Department of Internal Medicine & Rheumatology, Queen Elizabeth the Queen Mother Hospital, East Kent University Hospital, Margate, Kent, UK.

**Introduction**

Mycobacterium Chelonae is one of the rapidly growing non-tuberculous mycobacteria that can be isolated from water, soils and aerosols. Localized infections have been reported associated with tattoo parlors, pedicures and cosmetic procedures. But disseminated infection is usually associated with individuals who are immunocompromised, predominantly affecting limbs but sparing abdomen and back. We herein present a case where patient was on immunosuppressive therapy and developed locally severe infection around right ankle.

**Aims/Background**

Mycobacterium chelonae is known as a non-tuberculous environmental mycobacterium, belonging to the M. fortuitum complex, acid-fast bacilli, non-pigmented and with a fast rate of growth; it was first isolated from a sea turtle named Chelona corticata, but it is usually found in the water, soil, dust and contaminated instruments. There are multiple reports of this infection after trauma, surgical procedures and other procedures including acupuncture, pedicures, subcutaneous injections, pacemaker implants. It can cause both soft tissue and skeletal infections in healthy individuals but disseminated infection usually occurs only in immunosuppressed patients. Clinical manifestation can vary from local abscess or ulcer formation to multi organ involvement. Diagnosis is confirmed by taking biopsy sample of affected tissue, Ziehl-Neelsen staining, histopathological examination, molecular biology methods, culture in appropriate mediums and RNA probes. These non-tuberculous mycobacteria are resistant to conventional anti tuberculous drugs and there is no randomized controlled study to suggest particular therapy for these infections, however four to six months of clarithromycin has been prescribed successfully previously with very few cases of resistance.

**Method**

first acute flare of Lupus, Second atypical Infection post chemotherapy involving skin and muscles. Third was Malignancy

**Results**

She was admitted for triple regimen as per microbiologist guidelines. She was started on Intravenous tobramycin, imipenem and clarithromycin. Non-tuberculous mycobacteria are resistant to conventional antituberculous drugs. Likely course of treatment will be at least six to twelve months depending upon response to therapy

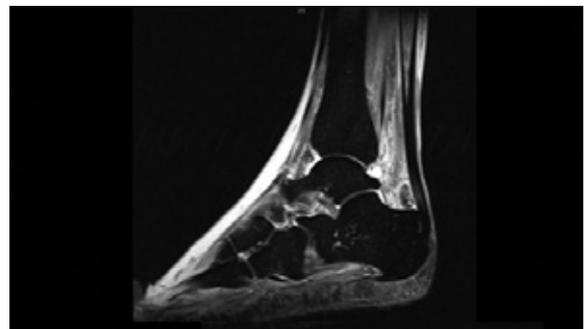
**Conclusions**

- Locally aggressive infection or disseminated disease warrants treatment from 6 to 12 months as per drugs susceptibilities.
- Best medications to consider for M. Chelonae are Tobramycin, Imipenem, Clarithromycin, Linezolid, co-trimoxazole.
- Multiorgan involvement is must to be ruled out, as it can cause mortality if it disseminates and involve lungs particularly

Figure



Figure



(19A122) ABSTRACT 57

CASE POSTER 49

**Pyoderma Gangrenosum & Leukocytoclastic Vasculitis as a Rare Complication of Flu Vaccination in a Patient with Psoriatic Arthritis**

**Author(s)**

Dr Sheraz Rasool, Dr Harsharan Kaur, Dr Denise De Lord.

**Department(s)/Institutions**

Department of Internal Medicine & Rheumatology, Queen Elizabeth the Queen Mother Hospital, East Kent University Hospital, Margate, Kent, UK.

**Introduction**

We report a rare complication of LCV and pyoderma gangrenosum in a patient with psoriatic arthritis 5 days after immunization with a quadrivalent influenza vaccine. Humira and methotrexate had been stopped several months earlier peri-operatively. The skin biopsy confirmed the diagnosis of Leukocytoclastic vasculitis. Despite high dose intravenous and oral steroids, the rash progressed with the development of Pyoderma Gangrenosum. Resolution of the rash only occurred on re-starting immunosuppressive therapy.

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Severe, active and progressive RA without prior methotrexate treatment. **Psoriatic arthritis (PsA):** Treatment of active and progressive PsA in adults when response to previous DMARDs has been inadequate. **Axial spondyloarthritis; Ankylosing spondylitis (AS)** Treatment of adults with severe active AS who have had an inadequate response to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Treatment of adults with severe nr-axSpA with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs). **Plaque psoriasis (PP):** Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy, including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). **Children aged 2-17 years: Juvenile idiopathic arthritis (JIA),** Polyarthrit (rheumatoid factor positive or negative) and extended oligoarthritis when inadequate response to, or intolerant of methotrexate. PsA from the age of 12 years when inadequate response to, or intolerant of conventional therapy. **Children aged 6-17 years:** Paediatric plaque psoriasis (ppp) when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Administration and dosage:** By subcutaneous injection **Adults:** RA - 25 mg twice weekly or 50 mg once weekly, PP - 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS, nr-axSpA and PsA - 25 mg twice weekly or 50 mg once weekly. **Children aged 2-17 years:** JIA - 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 - 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. **Children aged 6-17 years:** PPP in children aged 6-17 years - 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Benepali is not for use in children and adolescents who weigh less than 62.5 kg.** **Contraindications:** (1) Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. (2) Sepsis or risk of sepsis. (3) Active infections, including chronic or localised infections. **Warnings and Precautions:** Patients treated with BENEPALI should be given the Patient Alert Card (PAC), found in the treatment pack. Record the batch number and trademark in the patient file. 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a malignancy during treatment. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF antagonists, including etanercept. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with etanercept. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. **Vaccinations:** Live vaccines should not be given concurrently with BENEPALI. 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Discontinue BENEPALI treatment if blood dyscrasias are confirmed. **Neurological disorders:** A risk/benefit evaluation is recommended when prescribing BENEPALI to patients with pre-existing or recent onset CNS demyelinating disease, peripheral demyelinating polyneuropathies, or to those who are considered to have an increased risk of developing demyelinating disease. **Combination therapy:** The long-term safety of etanercept in combination with DMARDs other than methotrexate has not been established. The use of etanercept in combination with other systemic therapies or phototherapy for the treatment of psoriasis has also not been studied. **Renal and hepatic impairment:** No dose adjustment is required in patients with renal or hepatic impairment. **Congestive heart failure (CHF):** Caution when using Benepali in patients who have CHF. Inconclusive data suggest a possible tendency toward worsening CHF in etanercept treated patients. There are also rare reports of new onset CHF, including CHF in patients without known pre-existing cardiovascular disease. **Alcoholic hepatitis:** Caution when treating patients with BENEPALI who also have moderate to severe alcoholic hepatitis. Do not use BENEPALI to treat alcoholic hepatitis. **Wegener's granulomatosis:** BENEPALI is not recommended for use in patients with Wegener's granulomatosis. **Hypoglycaemia in patients treated for diabetes:** There have been reports of hypoglycaemia following initiation of etanercept in patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. **Elderly (> 65 years):** There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with etanercept. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy and lactation:** Women of childbearing potential should use appropriate contraception to avoid becoming pregnant during BENEPALI therapy and for three weeks after discontinuation of therapy. BENEPALI is not recommended in pregnant or breast-feeding women. **Drug interactions:** BENEPALI is not recommended in patients being treated with anakinra or abatacept. 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Please refer to the SmPC for other serious, paediatric and less commonly reported adverse events. **Legal Classification:** POM **Pack Size: Package Quantities:** BENEPALI pre-filled syringe: Each carton contains 4 pre-filled syringes of 25 mg OR 50 mg of Benepali clear glass (type I) syringe with stainless steel needle, rubber needle cover and plastic plunger. Each syringe contains a 25 mg OR 50 mg dose of etanercept. BENEPALI pre-filled pen: Each carton contains 4 pre-filled pens. Each pre-filled pen contains a pre-filled syringe containing 50 mg of BENEPALI. 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Reference: 1. Medicines Management Programme Best-Value Biological Medicines: Tumour Necrosis Factor-α Inhibitors on the High Tech Drug Scheme 2nd May 2019

2. Biogen data on file as of June 30, 2019

3. Biogen Q2 2019 earnings presentation

\*ETN= Etanercept

\*\*5 largest European countries in market size: UK, Germany, Italy, France and Spain

†Medicines Management Programme

Biogen-22404 Date of Preparation August 2019 IE



### Aims/Background

Leukocytoclastic vasculitis is categorized as small vessel vasculitis that presents with a skin rash in form of palpable purpura mostly on the lower limbs. The most common triggering factors are exposure to an infection or a new medication. In many cases, the cause is not identified. This is the first case report of the development of LCV and Pyoderma gangrenosum post flu vaccination in a patient with psoriatic arthritis. Early recognition of the association with the vaccination, rapid treatment and reinstatement of immunosuppressive therapy resulted in rapid resolution of the cutaneous vasculitis and PG.

### Method

Although rare, LCV is a recognized adverse effect following flu vaccination. Early diagnosis and treatment can prevent prolonged hospital stay and morbidity. This is the first case report of the development of LCV and Pyoderma gangrenosum post flu vaccination in a patient with psoriatic arthritis under 50 years of age. There is an increased risk of mortality secondary to influenza in those who are immunocompromised. Temporary cessation of immunosuppressive therapy in this patient may have precipitated the development of LCV and PG.

### Results

The patient was treated aggressively with intravenous Methylprednisolone and later high dose oral prednisolone. Methotrexate was re-started when infection was excluded and then adalimumab on diagnosing pyoderma gangrenosum. The leukocytoclastic vasculitis responded to intravenous steroid but complete resolution of the pyoderma gangrenosum only occurred on re-instituting adalimumab and Methotrexate. The rash has now resolved completely with only residual scarring.

### Conclusions

This is the first case report of the development of LCV and Pyoderma gangrenosum post flu vaccination in a patient with psoriatic arthritis. Caution should therefore be exercised in administering flu vaccines to patients who have had their biological therapy temporarily discontinued.

Re administering flu vaccine to such patients should be carefully considered with discussion with the patient of the pros and cons of flu vaccination, morbidity and mortality of flu itself.

Figure



### (19A124) ABSTRACT 58

### CASE POSTER 50

## Disseminated Pneumococcal Infection in an Immunocompromised Rheumatic Disease Patient

### Author(s)

Kieran Murray, Anna O'Rourke, Candice Low, Eoin Feeney, Eric Heffernan, Douglas J Veale

### Department(s)/Institutions

Saint Vincent's University Hospital

### Introduction

An 88-year-old woman with RA on adalimumab presented to the Emergency Department unwell for three weeks. Initial symptoms were fatigue, jaw and elbow pain. She was commenced on oral ibuprofen and prednisolone by her GP for a suspected RA flare but failed to improve. In the four days prior to hospital presentation, she developed fevers, headaches, vomiting, rigors and somnolence.

On admission, she was febrile with meningism, confusion, global weakness and a tense warm left elbow effusion. She had elevated neutrophils (18.6 x10<sup>9</sup>/L) and C-reactive protein (364 mg/L). Left elbow X-ray was suggestive of an olecranon bursitis. CT brain with contrast revealed a right infratemporal fossa fluid collection extending into the right temporomandibular joint (TMJ) and a left cerebellar lesion consistent with an abscess. CSF showed 13 white cells per cmm (99% polymorphs), red cell count of 8 per cmm, protein 3.27g/L (normal 0.15-0.45) and glucose 0.1mmol/L. Cefotaxime, vancomycin, dexamethasone and intravenous fluids were commenced. Adalimumab and prednisolone were discontinued.

### Aims/Background

Pneumococcal urinary antigen was positive. CSF and left olecranon bursa aspirates showed gram positive cocci. Streptococcus pneumoniae was cultured from blood (Image 1), CSF and left olecranon bursa cultures. The patient had never received pneumococcal vaccination. Ultrasound showed effusions superficial to the left olecranon (Image 2) and in the TMJ. MRI brain showed a hyperintense rim enhancing fluid collection extending around the right neck of the mandible.

### Method

The patient was treated with IV cefotaxime and had three drainages of her olecranon bursitis. Otolaryngology and maxillofacial surgery advised conservative treatment of her TMJ effusion and abscess.

### Results

After 28 days IV cefotaxime, she was transitioned to oral amoxicillin and discharged to community rehabilitation. She made a full recovery and remains off immunosuppression.

### Conclusions

This patient had a life-threatening case of disseminated pneumococcal infection with an infected olecranon bursitis, meningitis, TMJ effusion, left cerebellar lesion and bacteraemia. This was on the background of iatrogenic immunosuppression without recommended vaccination. The case highlights the importance of vaccinating immunosuppressed rheumatic disease patients.

Figure

Image 1. Growth of patient's blood cultures on a blood agar plate



Small, grey, moist colonies of diplococci with a characteristic zone of alpha-hemolysis, consistent with *S. pneumoniae*.



Figure



Image 2. Ultrasound left elbow  
A complex effusion within a thick-walled bursa (arrows) superficial to the olecranon (\*). There is hyperaemia in the wall of the bursa on this colour Doppler image, as well as in the surrounding soft tissues.

(19A126) ABSTRACT 59

CASE POSTER 51

### A case of relapsing polymyositis associated with anti-TIF1 gamma antibody

#### Author(s)

Dr Aqeel Maqsood Anjum Dr Alwin Sebastian Dr Wan Lin Ng Dr Cillian Hurst Dr Joe Devlin Dr Alexander Fraser

#### Department(s)/Institutions

Department of Rheumatology University Hospital Limerick

#### Introduction

Idiopathic inflammatory myopathies (IIMs) are a group of autoimmune, rare and heterogeneous muscle disorders characterized by presence of proximal and symmetrical muscle weakness which can result in impaired endurance and disability. Polymyositis is one of the several idiopathic inflammatory myopathies. Anti-TIF1 gamma antibody has been proven to be independently associated with cancer in IIMs.

#### Aims/Background

We present a case of 62 years old Caucasian lady who presented in July 2017 with 4 months history of progressively worsening fatigue, muscle aches, body stiffness, reduced mobility and unintentional weight loss. She had a background history of IDDM, CKD-III, diabetic retinopathy, significant ischemic heart disease. She was insulin, DAPT and high dose atorvastatin. Only objective finding was proximal weakness with mild tenderness. Her initial workup results are shown in Fig 1.

MRI thigh confirmed significant inflammation in thigh muscles.

#### Method

She was treated with IV Methylprednisolone followed by oral prednisolone and methotrexate with extensive physiotherapy. There was great clinical and serological response. CTTAP did not show any significant abnormality and OGD was suggestive of gastritis. Methotrexate was changed with Cellcept in October 2017 after first flare. Because of persistent disease activity she was given rituximab. There was good response to rituximab initially but she presented in hospital gain with major flare of Polymyositis in February 2019.

#### Results

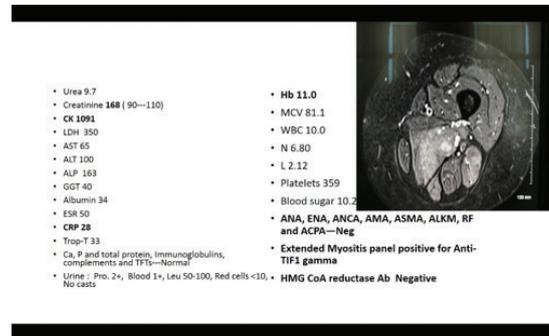
This time she was given IVIG along with high dose IV steroids. During this admission muscle biopsy and EMG were suggestive of Polymyositis. There was no evidence of any malignancy on CT TAP and PET CT. After 4 monthly doses of IVIG, she has been in sustained remission on prednisolone 7.5 mg and plaquenil 200 mg BD. Fig 2

#### Conclusions

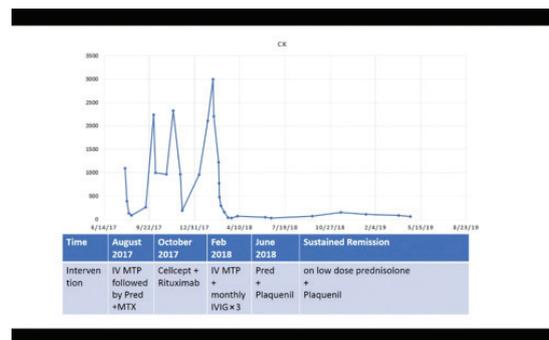
Treatment of Polymyositis can be very challenging particularly in the presence of comorbidities. Defining the optimal treatment regimens for these disorders has been difficult because of the rarity of these disorders, their highly complex clinical phenotypes, and the limited

number of randomized, double-blind clinical trials. It is important that neoplasm screening should be regularly performed not only at diagnosis, but also during follow up, for at least 5-10 years, even though neoplasia risk is maximum during first year after diagnosis.

Figure



Figure



(19A131) ABSTRACT 60

CASE POSTER 52

### An unusual presentation of vasculitis

#### Author(s)

Dr Sharon Cowley Dr Shawn Chavrimootoo Dr Sekharipuram Ramakrishnan

#### Department(s)/Institutions

Regional Department of Rheumatology, Navan

#### Introduction

ANCA associated vasculitis has a worldwide reported incidence of 1.2 – 2.0 cases per 100,000 and prevalence of 4.8 – 18.4 cases per 100,000. Patients typically present as a multi-systemic disorder with a variety of symptoms including rash, fever, fatigue, arthritis, lung involvement and renal involvement. Cardiac manifestations are generally considered rare in ANCA vasculitis but they are described in the literature and can be life threatening. Cardiac presentations as the sole manifestation of ANCA vasculitis is even rarer.

#### Aims/Background

A 69 year old retired insurance broker presented to our Emergency Department with shortness of breath on exertion and chest pain. The episode occurred once while walking to work. He attended his GP who referred him to ED for assessment. The chest pain was central with no radiation, 4/10 severity, and resolved after one hour with rest. It was pleuritic in nature. His past medical history included gout, gastroesophageal reflux and hyperlipidaemia. His medications included allopurinol 300mg OD and pantoprazole 40mg OD.

#### Method

His initial investigations included an electrocardiogram which



showed ST segment elevation in the inferior leads of <1mm. Serial troponins were completed which were <1 ng/L. Other bloods completed including an ESR of 71mmHg and c-reactive protein of 206mg/l. Vasculitic screen showed a positive ANCA with MPO pattern.

#### Results

Echocardiogram was performed which showed a moderate pericardial effusion. CT thorax, abdomen and pelvis was further completed showing a large tense pericardial effusion with nil otherwise significant abnormalities. The patient was referred to Nephrology in Beaumont hospital based on positive dipstick findings of blood and protein. This was repeated in Beaumont and had normalised. Renal biopsy was not pursued. The patient was initiated on steroids and subsequently on mycophenolate mofetil and titrated to 1g BD. Follow up echocardiogram was completed after one month showing almost complete resolution of pericardial effusion.

#### Conclusions

The French Vasculitis Group published a retrospective analysis in 2015 of 671 patients with Granulomatosis with Polyangiitis (GPA) of which 39 (5.8%) had cardiac manifestations at diagnosis. Pericarditis as a sole presentation is extremely rare with very few cases reported in the literature.

(19A132) ABSTRACT 61

CASE POSTER 53

### Anti-TNF induced Sarcoid like illness

#### Author(s)

Dr Sharon Cowley Dr Sekharipuram Ramakrishnan Dr Shawn Chavrimootoo

#### Department(s)/Institutions

Regional Department of Rheumatology, Navan

#### Introduction

A 22 year old lady was referred to the Rheumatology service from Dermatology with swollen fingers and toes on a background of Psoriasis since age 13. She had a one year intermittent history of left index finger swelling and right second toe swelling, with associated pain. She also had lower back pain which was inflammatory in nature, with associated early morning stiffness of 2-3 hours per day.

#### Aims/Background

Past medical history included light treatment for psoriasis, left pelvic kidney and unicorn uterus. She was a current smoker.

#### Method

On examination she had synovitis to left second PIP and MCP joints and Left 3rd DIP joint. Dactylitis was present to the right 2nd toe and left big toe. There was evidence of active psoriasis to the elbows, knees and lower legs. She had psoriatic nail changes. Schober's test was 6cm and FABER test was positive on the left, with bilateral sacroiliac joint tenderness, left more pronounced than the right. Bloods at initial assessment were unremarkable.

#### Results

She was commenced on methotrexate 15mg weekly plus folic acid 5mg weekly along with etoricoxib 90mg daily for the dactylitis. She was also worked up with MRI spine and sacroiliac joints which showed bilateral acute sacroiliitis. She subsequently stopped methotrexate secondary to gastrointestinal side effects. She was worked up for biologic and certolizumab was commenced. One year later the patient presented to the Emergency Department with a three month history of night sweats, palpitations and approximately twelve kilograms of weight loss.

Routine bloods were completed which were normal. CT thorax, abdomen and pelvis was further completed and showed clear pulmonary fields. Large lymph nodes were present in the mediastinum and both axilla. An endobronchial ultrasound and biopsy was completed which demonstrated non-necrotising granulomas,

consistent with sarcoidosis or related to TNF-alpha inhibitor.

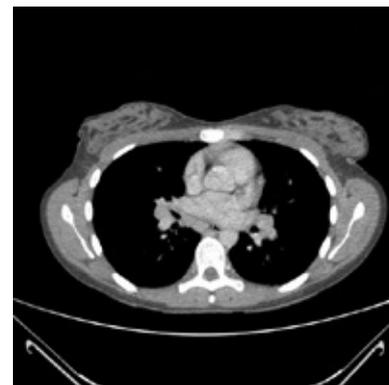
#### Conclusions

Rapid resolution of symptoms was achieved on stopping the offending agent. The patient has since been commenced on an alternative anti-TNF with no recurrence.

Figure



Figure



(19A136) ABSTRACT 62

CASE POSTER 54

### Case report on a rare presentation of Gout involving the Patellar tendon

#### Author(s)

Dr Asif Munir Dr Claire Sheehy Dr Donncha O'Gradaigh Dr Michael Farrel

#### Department(s)/Institutions

Department of Rheumatology, University Hospital Waterford  
Department of Radiology, University Hospital Waterford

#### Introduction

Gout is an inflammatory arthropathy associated with long-standing hyperuricemia. The first metatarsophalangeal joint is the most commonly involved joint, although gout is often polyarticular. Involvement of tendons has been described, but is rare. We report a case of gout involving the inferior portion of the patellar tendon.

#### Aims/Background

Case report

#### Method

A 50 years male presented to the Rheumatology emergency clinic with severe right knee pain, unable to weight bear. He had been recently diagnosed with Sero negative Inflammatory Arthritis and treated with Methotrexate for 4 months. He had presented one week previously to the general medical team on call with similar but less severe pain. He was discharged on steroids, which were of no significant benefit. On examination his right knee was extremely tender, slightly erythematous with increased local temperature. There was no joint involvement and there were no tophi. Joint aspiration

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was attempted but there was no fluid. He was admitted with query Septic arthritis and started on intravenous antibiotics. Uric acid level was 583. He was taken to theatre by the orthopaedic team. USG of the knee showed small fluid in the pre patellar bursa. Aspirate was negative for crystals and there was no growth on Cultures. He ultimately had an MRI of his right knee which showed significant soft tissue oedema and abnormality in the patellar tendon (image 1). Targeted USG of the knee done by a consultant rheumatologist showed significant changes in the inferior portion of the patellar tendon consistent with infiltration. The external tendon boundaries were normal. It was thought to be likely that these represented gouty tophi (Image 2). He went on to have a patellar tendon biopsy which has shown changes consistent with gout. He was started on Colchicine 0.5mg bd leaving the hospital and Allopurinol was started two weeks later.

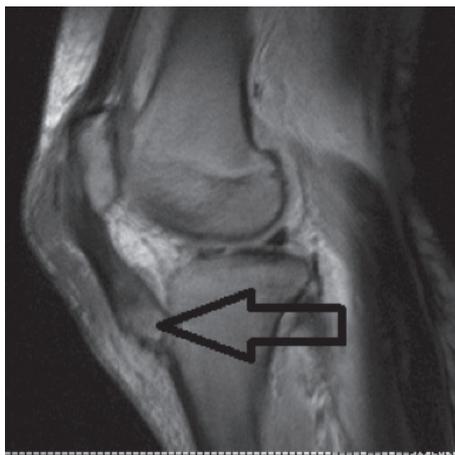
**Results**

He was seen in the clinic as follow up with complete resolution of his pain. Methotrexate was stopped. He has reported no flares and allopurinol is being titrated up to achieve serum uric acid concentration <300u/l.

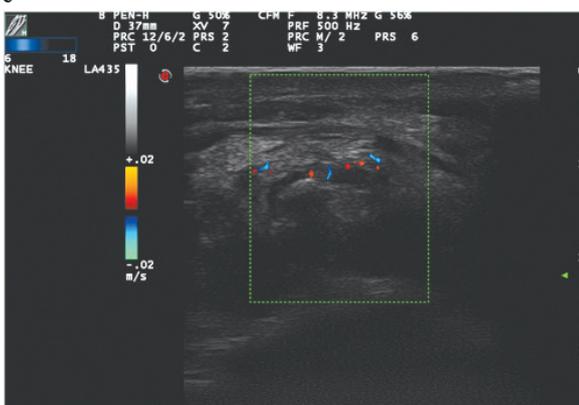
**Conclusions**

This case report is to highlight the rare presentation of gout.

Figure



Figure



(19A139) ABSTRACT 63

CASE POSTER 55

**Not all odontoid is rheumatoid**

**Author(s)**

Dr Sharon Cowley Dr Shawn Chavrimootoo Dr Sekharipuram Ramakrishnan

**Department(s)/Institutions**

Regional Department of Rheumatology, Navan

**Introduction**

Precipitation of crystals of calcium pyrophosphate dihydrate in connective tissues is associated with several clinical syndromes including acute inflammatory arthritis, degenerative chronic arthropathies and subclinical radiographic abnormalities.

**Aims/Background**

A 76 year old lady presented to ED with a four day history of left knee swelling and left sided neck pain. She attended her GP and was prescribed coamoxyclav 625mg TDS and solpadeine 8/30/500mg two tablets QDS. She then developed diarrhoea, vomiting and reduced oral intake. Energy was reduced and she was unable to mobilise secondary to generalised weakness. She was seen on a GP house call one week after initial consultation and was then referred to the emergency department.

Left knee swelling occurred spontaneously in the absence of trauma, 6/10 severity with associated stiffness. Left sided neck pain radiated to the left post auricular region, 10/10 severity with no associated headache, jaw claudication or visual disturbance. She denied temperatures, rashes or any other joint pain. Her background history included hypertension, hiatus hernia, B12 deficiency, cholecystectomy, and asthma. Her medications on admission included ramipril 5mg OD, indapamide SR 1.5mg OD, esomeprazole 40mg OD, calcichew tablet OD, B12 injections weekly, relvar ellipta inhaler 92/22mcg OD, denosumab 60mg 6 monthly.

**Method**

Bloods on admission were unremarkable apart from a c-reactive protein of 109.7mg/l, ferritin of 567ng/ml. X-rays were completed to evaluate her neck and knee pain. Bilateral knee xrays showed mild degenerative change and chondrocalcinosis. X-ray of the cervical spine showed degenerative changes in the facet joints in the mid cervical spine.

**Results**

The patient deteriorated with spiking fevers, crp rise to >300 and increasing neck pain and tenderness over C1-C2. She was reviewed by orthopaedics who recommended IV antibiotics for presumed discitis. She had an MRI spine which showed oedema and erosion of the odontoid, appearances suggestive of rheumatoid arthritis. CT was subsequently performed showing calcification of the alar ligament with arthropathy and erosive change most compatible with CPPD disease.

**Conclusions**

This case highlights the varied presentation of CPPD disease. Spinal CPPD disease is often overlooked. Radiology was particularly helpful in the final diagnosis.

(19A152) ABSTRACT 64

CASE POSTER 56

**Corneal Melt- don't always blame Rheumatoid Arthritis (RA)**

**Author(s)**

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**Department(s)/Institutions**

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**Introduction**

Corneal melt is a rare inflammatory disease of the peripheral cornea; it may lead to perforation of the globe and visual failure. Corneal melt can be a manifestation of systemic vasculitis in patients with RA and other conditions, such as cancer. Without early and aggressive treatment it may be associated with a poor visual outcome and high mortality. It has been reported in patients with stable RA.

**Aims/Background**

Case report



### Method

A 75 year old male with a background of sero positive Rheumatoid Arthritis presented to the Eye Casualty with a two week history of a painful left red eye. His other medical history was significant for Stage IIB poorly differentiated cancer of the left lower lobe since 2017. He was awaiting biopsy of renal mass ?metastatic lung disease vs primary renal carcinoma. His RA was well controlled on Methotrexate 10mg weekly. He described sharp eye pain, waking him from the sleep, associated with watery discharge and photophobia. He had been treated by the ophthalmology team for left marginal Keratitis for the past 2 months with steroid eye drops. Examination showed corneal melt in left eye involving 25% of inferior portion of the cornea and spastic entropion with injecting eye lashes. CRP was 4.1. He had a negative ANA and ANCA; viral swabs were negative. He had no active joints and there were no other signs of vasculitis He was admitted under the medical team. Intravenous Methyl Prednisolone was started. The patient felt better after 5 days of Methyl Prednisolone. Cyclophosphamide was initiated after discussion with Oncologist pending the result of the renal biopsy.

### Results

The renal biopsy was positive for metastatic Squamous Cell Carcinoma of lung. The cornea improved with complete resolution of his visual symptoms.

### Conclusions

In this case, although the history of RA was felt by the ophthalmology team to be the most likely association with the corneal melt, we would argue the oncological diagnoses were likely the driving force behind the presentation.

### (19A153) ABSTRACT 65

### CASE POSTER 57

### Targeting therapy to anticipated phenotype, based on autoantibody profile, in early amyopathic dermatomyositis. A case report.

#### Author(s)

Dr Karl Kavanagh, Dr Laura Durcan

#### Department(s)/Institutions

Beaumont Hospital, Dublin

#### Introduction

An emerging body of evidence supports the stratification of therapies in dermatomyositis according to phenotype and antibody subtype. Here we describe the novel case of very early interstitial lung disease associated with classic MDA5 subtype dermatomyositis and our therapeutic approach.

#### Aims/Background

A 22 year old male with a past history of type 1 diabetes presented with an erythematous rash across the dorsum of his hands, digital swelling and generalised, mild, early morning stiffness.

His hands were diffusely swollen with small ulcers at the tips of multiple digits. His rash was scaly and worst across his knuckles associated with ulceration. His face demonstrated a similar erythematous scaly rash along the hair line with erythema of the scalp and at the nape of the neck. His CK was normal as were inflammatory markers. The differential was of dermatomyositis with prominent cutaneous involvement or perhaps psoriasis given the scale and question of dactylitis. He was commenced on methotrexate and a tapering dose of steroids.

#### Method

Case report

#### Results

Investigations demonstrated positive Ro and Ro-52 antibodies with marginally low C4. An MRI of his thigh demonstrated some mild muscle oedema in the vastus lateralis which was nonspecific, EMG and muscle biopsy were normal. Pulmonary function testing

demonstrated a slightly decreased DLCO (86%) with normal volumes. A CT thorax showed subtle subpleural and peribronchovascular groundglass change in the costophrenic regions which persisted on prone views. This was suggestive of early interstitial lung disease.

#### Conclusions

Given his antibody subtype ( Ro 52/MDA5 ) which is known to be associated with a severe spectrum of amyopathic dermatomyositis with cutaneous ulceration with prominent pulmonary involvement and high mortality, we changed him to Mycophenolate Mofetil and worked him up for Rituximab.

Dermatomyositis associated with MDA5 positivity is characterised by prominent cutaneous findings, including in particular cutaneous ulceration and calcification and interstitial lung disease. Given the severity of the lung disease described in this disease subtype and the associated mortality we proceeded with aggressive immunosuppression despite mild pulmonary involvement. At the time of this case the patient has had almost complete resolution of his cutaneous disease and follow up imaging is pending.

### (19A159) ABSTRACT 66

### CASE POSTER 58

### Atypical presentation of small intestine neuroendocrine tumour previously diagnosed as eosinophilic fasciitis

#### Author(s)

Loai A Shakerdi, Aadil Al Ghafri, Niall Swan<sup>1</sup>, Donal O'Shea<sup>2</sup>, Michael Hutchinson<sup>3</sup> and Oliver FitzGerald

#### Department(s)/Institutions

Departments of Rheumatology, Pathology<sup>1</sup>, Endocrinology<sup>2</sup> and Neurology<sup>3</sup> St Vincent's University Hospital, Dublin

#### Introduction

Herein we report a follow up of a case published in Neurology in February 2003. The patient presented at that time with facial pain and swelling extending down to the left side of neck and to the upper chest wall. A temporalis muscle biopsy was consistent with Eosinophilic Fasciitis (EF), responding well to corticosteroids and methotrexate. The condition followed a relapsing-remitting pattern over 15 years with facial and limb pain and swelling, before developing frequent episodes of abdominal pain with massive distension. CT scan and histopathology revealed three separate, well-differentiated neuroendocrine tumours (NET's). Tumour resection resulted in complete resolution of all previous symptoms over 18 months follow-up and post-operative OctreoScan was negative.

#### Aims/Background

NETs are a widely heterogeneous group of neoplasms which develop in several organs, predominantly in the gastroenteropancreatic (GEP) system. The diagnosis of GEP-NETs is based on clinical symptoms, hormone levels, radiological and nuclear imaging and histological confirmation. GEP-NETs are classified according to the primary tumour site, their functionality and histology.

EF is an uncommon disorder of the fascia of unclear aetiology and pathophysiology. Usual presentation is with an abrupt onset of symmetrical tenderness and swelling of the extremities, rapidly followed by induration of the skin and subcutaneous tissue.

#### Method

The patient underwent Laboratory investigations, Radiology, Histopathology and Immunohistochemistry

#### Results

CT scanning showed some mid-gut mucosal thickening with associated lymphadenopathy which was all surgically resected. Histopathology revealed three separate, well-differentiated neuroendocrine tumours (NET's), the largest of which had invaded into sub-serosal tissue. In addition, a 35mm mesenteric tumour deposit was present with two of four lymph nodes containing metastatic NET (Figure 1). The proliferation index of both the primary and metastatic tumour, as measured by Ki67 immunohistochemistry, was <2%. The final



pathological stage was pT3(m)N1Mx.

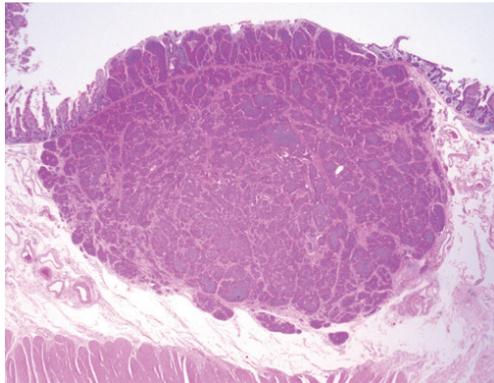
Image 1: Well differentiated neuroendocrine tumour invaded into sub-serosal tissue (HE 16X)

Image 2: 200X Immunohistochemical staining positive for Chromogranin

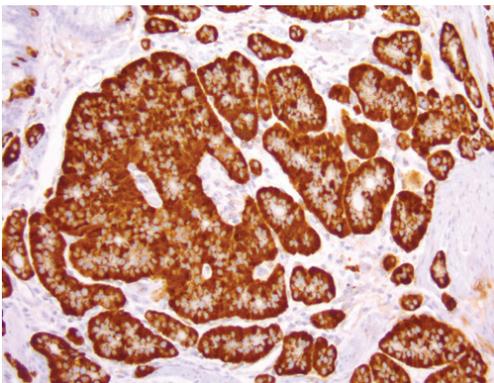
**Conclusions**

The initial clinical presentation here was not typical of EF and all of the symptoms including those previously ascribed to EF resolved with NET resection confirming the NET as a unifying diagnosis.

Figure



Figure



(19A161) ABSTRACT 67

CASE POSTER 59

**Resolution of complete heart block with immunosuppression in granulomatosis with polyangiitis (GPA). A case report.**

**Author(s)**

Connerton A, Glynn E, Durcan L, O’Connell P.

**Department(s)/Institutions**

Beaumont hospital, Beaumont, Dublin.

**Introduction**

We describe the case of a 78-year-old man, who presented to the emergency department with right conjunctival haemorrhage and severe right sided occipital headache.

He had a three month history of fevers, night sweats, weight loss, malaise, haemoptysis and productive cough, on a background of previously treated tuberculosis (1960’s). He was initially treated as a lower respiratory tract infection. His initial chest xray was within normal limits. A CT demonstrated peribronchial foci of groundglass opacification in the right considered to be either infectious or inflammatory with bilateral upper zone scarring granulomata in keeping with previous tuberculosis. His sputum was Ziehl-Neelsen stain negative. His symptoms worsened despite broad spectrum antibiotics.

He then developed respiratory distress, haemoptysis, small joint polyarthritis, epistaxis, and complete heart block (CHB). His repeat chest X-ray showed bilateral pulmonary haemorrhages (see Fig1) and his renal function deteriorated (Urea 17 Creatinine 185). His urine showed >100 RBC, P:CR ratio 205. Renal biopsy was deferred as he was too unwell and already fulfilled the diagnostic criteria for GPA, as immunologic testing demonstrated a strongly positive c-ANCA PR3 (titre=45). He remained in CHB with bradycardia and hypotension.

He was treated with prednisolone and Rituximab (1g x 2) with latent TB prophylaxis. His condition improved. His heart block resolved fully over three weeks with therapy suggesting that this was an infiltrative process. His creatinine stabilised at 155. His respiratory symptoms resolved.

This case highlights the multisystem nature of GPA and is unique in demonstrating resolution of complete heart block with treatment of same suggesting early identification of intraventricular conduction delays and prompt therapy may prevent permanent cardiac rhythmic dysfunction.



(19A164) ABSTRACT 68

CASE POSTER 60

**Recovery from severe dysphagia in polymyositis using Rituximab: a case report**

**Author(s)**

Fajer Altamimi, Usman Amin, Asif Munir, Donnoca O’Gradaigh, Claire Sheehy

**Department(s)/Institutions**

Rheumatology- University Hospital Waterford

**Introduction**

Polymyositis is one of the inflammatory myopathies. It is chronic autoimmune disease that usually involves the proximal muscles. It is caused by an inflammatory infiltrate of the skeletal muscle. Notably, Dysphagia occurs in one third of the patients.

Many rehabilitation and pharmacological measures for dysphagia have been tried to reduce the risk of aspiration. However, severe dysphagia should be managed by nasopharyngeal or gastric feeding tube. Also pharmacologically with high dose corticosteroids, other steroids sparing immunosuppressive agents, or intravenous immunoglobulins. However the role of Rituximab in the treatment of dysphagia was not clearly addressed.

**Aims/Background**

32 year old gentleman has known to have psoriasis and necrotizing polymyositis who suffered from severe dysphagia requiring percutaneous gastrostomy insertion.

He was treated with intravenous methylprednisolone, methotrexate and even intravenous immunoglobulins with no improvement. He is then tried on two doses of rituximab, when he started to show signs of improvement and eventually his tube was removed. Currently he is off medications.



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#### Method

It is a case report.

#### Results

The turn corner in our case when the patient started to tolerate full feeding after rituximab. We recommend conducting more researches using these agents in treatment of dysphagia

#### Conclusions

Dysphagia is one of the serious symptoms in patients with inflammatory myopathies and can be the presenting symptom. It was noticed that patients who required percutaneous endoscopic gastrostomy had a higher mortality rate.

In terms of management, Rehabilitation by a trained speech therapist should be tried. However, severe dysphagia should be managed by nasopharyngeal or gastric feeding tube to protect the airways and support the nutritional need.

Corticosteroids are the initial type of management in polymyositis. In case the patient required prolonged maintenance course, other steroid sparing agents should be tried. Interventional procedures such as cricopharyngeal myotomy found to be beneficial.

Having said that, reversal of dysphagia has not been clearly documented in the literatures with the use of rituximab. There is one case report mentioned the use of rituximab in systemic sclerosis – myositis. Accordingly, we suggest the need to evaluate the efficacy of rituximab in myositis-associated dysphagia.

(19A165) ABSTRACT 69

CASE POSTER 61

#### Intermediate uveitis, splenomegaly and cutaneous ulceration : Leprosy in modern Rheumatology practice

##### Author(s)

Lucy M Carter, Hudaifa Al-Ani, Samantha Line, Sri Sharma, Alexander Brand, Lorraine O'Neill

##### Department(s)/Institutions

Oxford University Hospitals NHS Foundation Trust

##### Introduction

We present a case which illustrates the epidemiology and clinical features of leprosy, as relevant to current Rheumatology practice.

##### Aims/Background

A 48 year old lady, originating from Timor Leste, presented to the Eye Hospital with subacute visual disturbance. Ophthalmology assessment revealed bilateral intermediate uveitis. The patient had no prior medical history and was on no regular medication. She had limited contact with health services since arrival in the UK six years previously. Further enquiry identified progressive skin lesions and 10 kg weight loss over the prior six months.

##### Method

Clinical examination revealed extensive well demarcated and relatively hypoalgesic cutaneous ulcers, below the knees bilaterally with surrounding hyperpigmentation. There was a solitary annular macule with central atrophy on the left upper arm and a subtle saddle nose deformity. Cardiorespiratory examination and vital signs were normal. Peripheral joint examination was unremarkable. There were no long tract signs and no clinically apparent neural thickening.

Cross sectional imaging confirmed clinical findings of 16 cm splenomegaly and bilateral lymphadenopathy confined to the inguinal region. Laboratory investigations showed severe anaemia Hb 53 g/L with iron deficiency haematinics and normal white cell differential. Routine clinical chemistry was normal. Acute phase markers were mildly elevated, CRP 16.2 mg/L. Serum ACE was significantly elevated at 132 U/L. HIV, syphilis and toxoplasma serology were negative.

#### Results

Microscopy of inguinal lymph node biopsy revealed non-caseating granulomata and numerous acid fast bacilli subsequently confirmed by culture and molecular techniques as mycobacterium leprae. Skin biopsy confirmed mycobacterial infection with chronic inflammation and extensive scarring. The patient was commenced on multidrug therapy.

#### Conclusions

Despite active worldwide leprosy elimination campaigns, areas of high endemicity persist and multisystem involvement may still bring this disease to the attention of the Rheumatologist.

(19A168) ABSTRACT 70

CASE POSTER 62

#### A fatal case of cryoglobulinemic vasculitis

##### Author(s)

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##### Department(s)/Institutions

Department of Rheumatology, Midlands Regional Hospital Tullamore

##### Introduction

A 90-year-old male patient presented to the emergency department in December 2018 with a rash on his chest present for 10 months. He also had noticed a rash on both lower limbs present for 4 days. He also was complaining of progressive discolouration of his toes bilaterally and severe pain in both feet.

There was associated weight loss of 3 stone over a period of 10 months. Of note he also had an episode of epistaxis on the day of presentation.

##### Aims/Background

He denied haematuria, haemoptysis, arthralgia or joint swelling. His past medical history was significant for advanced chronic lymphocytic leukaemia, for which he had never received any systemic treatment.

##### Method

He was seen by the rheumatology consult service and the following were noted.

On physical examination, there was bilateral above knee palpable maculopapular rash, conjunctival hyperemia, erythroderma over the abdomen and back, nailfold infarcts were noted as well as painful discoloured and necrotic toes. Cardiovascular, respiratory and gastrointestinal examinations were unremarkable. Musculoskeletal examination did not reveal any tender joints and no synovitis.

##### Results

Our impression was likely cryoglobulinemic vasculitis secondary to his underlying haematological malignancy.

He was started on IV methylprednisolone followed by oral steroids. He then received a first cycle of rituximab however his general state rapidly deteriorated and he eventually passed away after spending 19 days in hospital.

##### Conclusions

The treatment of cryoglobulinemic vasculitis must be individualized according to the underlying disorder and upon the severity and nature of involvement. In severe systemic disease, patients are treated aggressively with high dose steroids; immunosuppressants and/or plasmapheresis. The prognosis is usually poor with significant morbidity and mortality. The worst prognostic factors are advanced age (>60 years) and renal involvement.



Figure

ANA	Positive to titre > 1:160 (speckled pattern)	
ENA	Negative	
ANCA	Negative	
	MPO < 0.1 (nr < 5)	PR3 0.5 (nr < 3)
Anti-GBM antibody	< 0.1 U/ml (nr < 7)	
C3	0.95 (nr 0.9-1.8)	
C4	0.08 (nr 0.1-0.4)	
Serum protein electrophoresis	IgG kappa band, IgG lambda band, IgM Lambda band	
Viral serology		
Renal profile	Urea 40.1 (nr 2.8-8.1)	Creatinine 291 (nr 62-106)
CRP	17.9 (nr < 5)	
ESR	14 (nr < 14)	
White cell count	433.9 (nr 4-11)	
Neutrophil count	22.71 (nr 2-7)	
Haemoglobin	11.6 (nr 13.5-17.5)	
Platelet count	48 (nr 140-450)	
Urinalysis	Positive for protein, negative for blood	
CT thorax abdomen and pelvis	Widespread lymphadenopathy, hepatosplenomegaly	

(19A169) ABSTRACT 71

CASE POSTER 63

### Still Going Strong

#### Author(s)

Connerton A, Cole R, Glynn E, Durcan L, O'Connell P.

#### Department(s)/Institutions

Beaumont hospital, Beaumont, Dublin 9

#### Introduction

We present the case of a 73-year-old female with no past medical history who complained of three months of subjective fevers and malaise. A presumptive diagnosis of polymyalgia rheumatica had been made in primary care, based on axial stiffness and elevated inflammatory markers, and steroid therapy was initiated. At doses of 40 mg prednisolone per day her symptoms improved somewhat but deteriorated dramatically with any attempt to wean. She continued to complain of sore throat, fevers, and widespread joint pain and was admitted to hospital for further investigation.

Labs on admission were notable for elevated WCC (20.64), CRP(262), ESR(12), and hyperferritinaemia (12,588) with normal fibrinogen and triglyceride levels. CT thorax abdomen and pelvis demonstrated supraclavicular adenopathy. Bone scan showed tracer uptake bilaterally in knees, wrists and elbows likely degenerative. Non-specific tracer uptake in the medial aspect of her left ankle Her bone marrow showed an increase in macrophage population which did not meet the criteria for macrophage activation/ secondary haemophagocytic lymphohistiocytosis.

She was ultimately diagnosed as adult onset Still's disease fitting the Yamaguchi criteria, resistant to steroid taper and tocilizumab was initiated. She has improved significantly on tocilizumab, her inflammatory markers have settled and she is regaining mobility. (see table 1)

The diagnosis of adult onset stills disease is one of exclusion but is strongly suggested by extreme hyperferritinaemia in the absence of a malignant haematologic or severe infectious trigger. The importance of outruling macrophage activation is highlighted by this case and also the need to re-evalaute elderly patients with a label of PMR who are resistant to steroid taper

Figure

	Day 1	Day 10	Day 17
WCC	20.64	34.36	10.42
CRP	262	113	12
ESR	12	56	6
Ferritin	12,588	24,506	7930
Fibrinogen		3.7	4.4

Table 1.

↑  
After tocilizumab

(19A177) ABSTRACT 72

CASE POSTER 64

### Koebnerization of bone in a patient with multi-system sarcoidosis

#### Author(s)

Tahir Aziz1, Emma McDermott2, David Kane1, Ronan H Mullan1

#### Department(s)/Institutions

1. Department of Rheumatology, Tallaght University Hospital, Dublin 24 2. Department of Rheumatology. Our Lady's Hospital, Crumlin, Dublin 12

#### Introduction

Sarcoidosis is a multi system granulomatous disorder characterised by the presence of non-caseating granulomas in lung and extra thoracic tissues.

#### Aims/Background

Here we describe for the first time, the development of osseous sarcoidosis lesions following repeated minor nociceptive insults, consistent with sarcoidosis-induced Koebner phenomenon of bone.

#### Method

A 16 y/o patient with a previous history of thoracic and extra-thoracic sarcoidosis (biopsy-proven skin and nasopharyngeal involvement) successfully managed at Our Lady's Hospital, Crumlin with adalimumab and oral corticosteroids, presented to the adolescent Transition Clinic at Tallaght University Hospital. He reporting new swelling on the shaft of the right little finger within 24 hours of a trivial subcutaneous knife cut but which had since persisted for months.

#### Results

Examination revealed thickening of the right 5th middle phalanx with overlying violaceous discoloration of the skin. X-ray confirmed typical features of osseous sarcoidosis, with cortical expansion, osteolysis and trabecular thickening of bone (Fig 1). Three months later he presented with new persistent swelling of the distal phalanx of the right great toe after stubbing his toe on furniture. Clinical examination revealed swelling, with radiographic features consistent with new boney progression of osseous sarcoidosis of the great toe distal phalanx. Systemic features of sarcoidosis including pulmonary function tests, and serum markers have remained stable throughout. Dynamic technecium bone imaging and bone biomarker analysis are now awaited to assess bone disease activity, with a view to switching systemic sarcoidosis therapy.

#### Conclusions

Koebner phenomenon, also known as the Koebner or isomorphic response, refers to the development of skin lesions along previous lines of trauma, occurs in autoimmune diseases including psoriasis, vitiligo, lichen planus and sarcoidosis. Non-cutaneous Koebner lesions, including the oral mucosa, or at the site of internal organ scarring have been previously reported. This is the first documented case of osseous Koebner phenomenon, in two separate bones following repeated minor trauma. Prior nociceptive stimulus leading to the development of new bone lesions, indicates the likely involvement of neurogenic pain pathways in granuloma formation. Elucidation of the pathological mechanisms of osseous sarcoidosis may lead to potential new therapeutic strategies to treat this debilitating condition.

Figure



Figure 1. Osseous sarcoidosis of the R middle phalanx of the 5<sup>th</sup> digit is seen. Cortical expansion, trabecular thickening and osteolysis is seen.

(19A180) ABSTRACT 73

CASE POSTER 65

### Pneumatosis cystoides intestinalis in a patient with advanced scleroderma, a case report

#### Author(s)

Shamma Ahmad Al-Nokhatha, Muddassar Ahmad, Diana Ghetta, David Kane, Ronan H Mullan

#### Department(s)/Institutions

Department of Rheumatology, Tallaght University Hospital, Dublin, Ireland

#### Introduction

A 74-year old female fulfilling both anti-centromere positive limited systemic sclerosis and seropositive rheumatoid arthritis diagnostic criteria, presented to surgical services with nausea, vomiting, abdominal pain and constipation.

#### Aims/Background

Examination revealed abdominal distension without peritonism. Radiographic imaging showed volvulus with intestinal obstruction. Emergency laparotomy revealed a large portion of dilated and ischemic bowel without perforation. Bowel resection with end stoma formation was performed.

#### Method

Four months later the patient was readmitted with recurrent abdominal discomfort and subacute obstruction. Abdominal computed tomography (CT) showed both small bowel pneumatosis and residual small volume pneumoperitoneum attributed to recent surgery. Conservative management with bowel rest, fluid, electrolyte supplementation and parenteral nutrition were instituted with full resolution of symptoms. One-month later, the patient represented with a second episode of subacute small bowel obstruction. Repeat imaging showed interval progression of small bowel pneumatosis and new small bowel dilatation (Figure 1A, B).

#### Results

Rheumatology services were contacted and the patient was managed using high-flow oxygen therapy and antibiotics (rifaximine) to manage anaerobic bacterial overgrowth and the somatostatin analogue octreotide for intestinal pseudoobstruction. The patient's bowel symptoms resolved and she was weaned off oxygen. To date, her symptoms have not recurred.

#### Conclusions

Scleroderma is an autoimmune connective tissue disease affecting multiple organ systems. Gastrointestinal features are common, ranging from mild gastroesophageal reflux disease to life-threatening bowel dysfunction. Pneumatosis cystoides intestinalis (PCI) is a rare intestinal feature of scleroderma, characterized by gaseous cysts in intestinal submucosa, subserosa and surrounding tissues. PCI is presumed to occur secondary to overgrowth of anaerobic gas-

forming bacteria, which proliferate as a result of bowel stasis in the setting of intestinal fibrosis. Treatment strategies involve creating a toxic environment for anaerobic bacteria using rotating antibiotics and high-flow oxygen, as well as the use of pro-kinetic agents. An increased awareness of PCI among treating rheumatologists, along with the prompt institution of conservative management strategies, can prevent the requirement for surgical intervention leading to improve long-term outcomes.

Figure

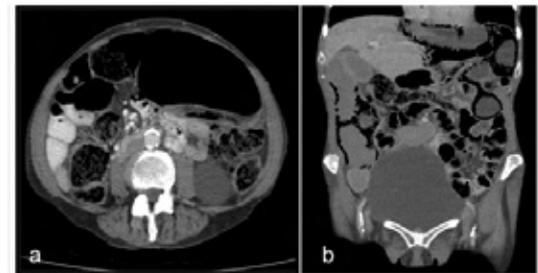


Figure 1. Pneumatosis Cystoides Intestinalis showing (a) toxic small bowel dilatation (b) submucosal and sub-serosal small bowel gaseous cysts.

(19A183) ABSTRACT 74

CASE POSTER 66

### Incomplete SAPHO Syndrome or Axial Spondyloarthritis

#### Author(s)

Qutab Shah, Sonia Sundanam, Aine Gorman, Angela Camon, Eileen Shinnors, Ausaf Mohammad and Killian O'Rourke

#### Department(s)/Institutions

Department of Rheumatology, Midlands Regional Hospital at Tullamore

#### Introduction

We describe a case of a 25 years old female with a history of Lumbar spine / sacroiliac joint / left ischial tuberosity pain since 2010, worse since 2016 (With prominent night pain). There was no history of weight loss, night sweats, fever, rash, ocular symptoms and peripheral joint swelling or pain. There was no history of Psoriasis and inflammatory bowel disease. Her previous medical history included Iron deficiency anemia and hypovitaminosis D. List of her medication included Naproxen 500mg, Esomeprazole, Vitamin D3, Paracetamol, and Etoflam gel. No smoking history. Family history was positive for Rheumatoid arthritis (mother affected) and Psoriasis and Psoriatic arthritis (brother affected). Lab investigations between 2016-2019 revealed negative HLAB27, ANA, RF, CCP, immunoglobulins, Hepatitis B, C, and TB Quantiferon. Normal renal, liver bone profiles, TFTs, B12, Folate, Ferritin and IgAtTG. Highest recorded CRP was 24.3 and ESR was 73 in 2016. Patient had only mild to moderate response to regular NSAIDs and a short course of steroids by GP. Imaging including CT Lumbar Spine, Abdomen/Pelvis and MRI Lumbosacral spine in 2016 was suggestive of osteomyelitis of left sacroiliac joint. Patient was thoroughly investigated by Infectious disease department in Dublin between years 2016-2018 and had a CT guided biopsies and aspirate of left SIJ in November 2016 and December 2018 which was negative for malignancy and infection including mycobacterium, Coxielle, Brucella, and Bartonella. However, it did show increased osteoblastic activity. No infiltrates. X-rays Chest and spine including cervical, thoracic, and pelvis/SIJ were noted normal. Subsequent MRI Lumbar spine /Pelvis and SIJ in November 2018 was again suggestive of left-sided erosive sacroilits and left ischial osteomyelitis but biopsy was negative for malignancy and infection. Isotope bone scan in Jan 2019 confirmed findings compatible with diffuse inflammation of left SIJ and sacral ala and also increased uptake at shoulders/AC/SC joints.



Based on MRI, CT and Isotope bone scan findings, she does have osteitis, hyperostosis and synovitis. Her bone biopsy did show some focal increased osteoclastic activity. However she does not have any history of acne or pustulosis. Therefore it is likely that the main differential for this patient's inflammatory arthritis could be SAPHO (Synovitis, Acne, Pustulosis, Hyperostosis, Osteitis) Syndrome which is a rare syndrome but it can cluster in families who are affected with psoriasis or psoriatic arthritis. The other possibility is an axial spondyloarthritis and she would be predisposed to this because of her family history of psoriasis and psoriatic arthritis. SAPHO Syndrome does not have any controlled data for any drug interventions. Treatment effectiveness is based on small studies of individual cases or case series for the most part but certainly anti TNF alpha drugs do seem to help these patients. Patient has been commenced on Anti-TNF in June 2019. Further details will be discussed.

**(19A186) ABSTRACT 75**

**CASE POSTER 67**

**"Now You See Me, Now You Don't". Large Lung Mass In Granulomatosis With Polyangiitis (GPA), responds rapidly to treatment**

**Author(s)**

Harkins P, Shah Q, Camon A, Wheelan E, Mohammad A, O'Rourke K.

**Department(s)/Institutions**

Midlands Regional Hospital Tullamore

**Introduction**

Granulomatosis with polyangiitis (GPA) is a multisystem non-caseating granulomatous c-ANCA positive vasculitis which often presents with pulmonary involvement. Prompt recognition is essential to limit organ damage.

**The Case**

We present the case of a 62-year-old gentleman with a 3-year background of GPA and rheumatoid arthritis (not currently taking prescribed medications), along with a thirty pack-year smoking history.

He presented to the emergency department with new onset dyspnea, fevers, arthralgia and a 13-kilogram weight loss over the previous one month period.

His inflammatory markers were elevated (CRP 27mg/L).

Chest X-ray (CXR) demonstrated consolidation in the posterior left upper lobe. Subsequent CT Thorax showed a large soft-tissue mass in the anterior aspect of the left upper lobe – suspicious for a bronchogenic carcinoma, with evidence of mediastinal and left hilar lymphadenopathy.

Whilst undergoing work-up for presumed primary lung carcinoma his symptomatic rheumatoid arthritis was treated with IV methylprednisolone.

He subsequently underwent bronchoscopy, broncho-alveolar lavage and fluoroscopy guided trans-bronchial biopsy of his lung lesion - all of which failed to diagnose a neoplastic process.

CXR repeated two weeks later showed that the previous consolidation had resolved. His CRP had normalized to 0.5mg/L. Follow up CT thorax was performed which showed significant improvement with the main anterior left upper lobe mass being completely resolved.

**Conclusion**

GPA often presents with pulmonary manifestations which range from mild upper respiratory tract symptoms to life-threatening pulmonary hemorrhage. The presentation in our case highlights the ability of GPA to mimic primary lung neoplasia which frequently requires invasive tests to further evaluate diagnostic possibilities. Rapid response to Steroids however is an important indicator that reversible, rather than sinister pathology is present. It is important that a flare of GPA be considered in the differential for a new and evolving lung mass.

**(19A187) ABSTRACT 76**

**CASE POSTER 68**

**An Incidental Finding Of Giant Cell Aortitis (GCA). A Case Report And Review Of The Literature.**

**Author(s)**

Harkins P, Shah Q, Camon A, Wheelan E, O'Rourke K, Mohammad A.

**Department(s)/Institutions**

Midlands Regional Hospital Tullamore

**Introduction**

GCA is the most common form of systemic vasculitis. Classically it affects the extracranial branches of the carotid arteries however it has the potential for large vessel involvement including the thoracic and abdominal aorta with increased risk of aneurysm and dissection.

**The Case**

We present the case of a 55-year old gentleman with a background of Ulcerative Colitis and associated HLA-B27 positive enteropathic arthritis. He was managed with regimens including adalimumab, methotrexate and prednisolone over a 6 year period since diagnosis.

He presented with a three week history of night sweats, unintentional weight loss and shortness of breath on exertion. His physical examination was unremarkable. He was found to have iron deficiency anemia. He underwent a thorough evaluation to rule out an underlying neoplastic process. This included colonoscopy which revealed a >1cm polyp in the sigmoid colon for which he underwent polypectomy. Histology revealed an invasive moderately differentiated adenocarcinoma with evidence of lymphovascular invasion and a positive resection margin.

In light of this histology he underwent staging combined PET-CT scanning of the thorax, abdomen and pelvis. This revealed abnormal wall thickening and linear uptake throughout the length of the thoracic and abdominal aorta consistent with aortitis.

Giant cell arteritis was confirmed on subsequent temporal artery biopsy, the histology of which was remarkable for a very high number of giant cells (Despite lack of headache and visual symptoms). Mr X underwent a successful sub-total colectomy for management of his colonic pathology. He was subsequently commenced on Rituximab to manage his GCA, with resolution of symptoms.

**Conclusion:**

This case highlights a less frequent presentation of GCA. In this case the diagnosis was found incidentally during workup for colorectal cancer.

We believe this case highlights that GCA should be considered in the differential for any patient 50 years or older presenting with unexplained fever, anemia or other constitutional symptoms or signs.

**(19A188) ABSTRACT 77**

**CASE POSTER 69**

**A challenging case of pyrexia of unknown origin**

**Author(s)**

Aine Gorman, Clarissa Fang, Tommy Tung, Trevor Duffy1, Maurice Barry, Carl Orr

**Department(s)/Institutions**

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**Introduction**

We present a case of a patient with lower limb pain and weakness. He went on to develop pyrexia of unknown origin The year prior to his presentation he had two admissions to hospital with pneumonia and with femoral plexus neuritis.

**Aims/Background**

A 69-year-old male presented with pain and weakness in both lower limbs in association with pitting oedema and weight loss for three months. The only positive features on clinical examination were marked tenderness in his lower limbs bilaterally, significant weakness and the absence of extensor hallucis longus power. There



was clear evidence of significant muscle wasting, especially in the thighs. He had widespread moderate wheeze on examination of his respiratory system. During his admission, he was noted to be pyrexial to 38.5C on a daily basis. He was initially treated with IVIG for likely Guillen-Barre syndrome.

His background history included asthma/COPD overlap syndrome. One year prior, he was admitted to hospital with evidence of a rash on his left lower limb consistent with varicella-zoster virus infection. Magnetic resonance imaging during that admission confirmed the presence of right femoral plexus neuritis. Six months later he had an inpatient admission with community-acquired pneumonia treated with antibiotics and steroids.

#### Method

ESR and CRP were raised at 51mm/hour() and 235 (0-5mg/L) respectively, with an associated neutrocytosis. Renal and liver blood profiles were normal. He was extensively cultured (blood x8, urine, CSF), microbiology serology and PCR, as well as imaging (CT TAP, TTE and TOE) did not reveal an infective aetiology. CK, complement, ANA were normal. Anti-MPO was positive at moderate titre. Whole-body MRI indicated 'myositis' of thigh muscles.

Biopsy of his left vastus medialis muscle revealed a possible vasculitis. A second biopsy was retrieved, and the neuropathologists concurred with the diagnosis of a small vessel vasculitis.

#### Results

He was treated as an ANCA-associated vasculitis- likely microscopic polyangiitis. After three months of tapering dose prednisolone and methotrexate, he has made a near-complete recovery.

#### Conclusions

This case highlights the challenges in diagnosing a defining disease in patients with non-specific symptoms and multiple presentations to hospital.

(19A189) ABSTRACT 78

CASE POSTER 70

### Drug Induced Midline Destructive Lesion and ANCA positive Vasculitis

#### Author(s)

Qutab Shah, Sonia Sundanam, Aine Gorman, Angela Camon, Eileen Shinnars, Ausaf Mohammad and Killian O'Rourke

#### Department(s)/Institutions

Department of Rheumatology, Midland Regional Hospital Tullamore

#### Introduction

We describe a case of a 24 years old male who was first seen in Rheumatology opd in March 2019 with a two years history of recurrent nasal obstruction, crusting, bleeding, nasal infections (Vestibulitis) and rhinosinusitis which responds partially to oral steroids / oral antibiotics / nasal sprays. However he feels that symptoms resolve mostly with oral steroid administration. He denied history of dry eyes, dry mouth, oral ulcers, paraesthesia of arms and legs, significant sputum production, symptoms suggestive of synovitis, vasculitic rash, or nail fold changes. He also reported weight loss of 9 kg and night sweats in recent months. His medical background history included childhood asthma and active heavy smoking. List of medication at included Prednisolone 15mg OD (On a reducing course to 0). Fluticasone Inhaler, Bactroban nasal ointment, and Montelukast. Family history was negative for inflammatory joint disease, Vasculitis and connective tissue disease. On physical examination he had some acneform lesions in his upper chest. There were no vasculitic lesions anywhere on the hands and feet. Cardiovascular, pulmonary and abdominal examination was unremarkable. He had some tenderness around his nose and sinuses on palpation. There was no lymphadenopathy. His nose did not look particularly erythematous but it did look enlarged. Lab investigations showed negative ANA, RF, anti-CCP, HLA B27, IgA, IgM, and normal C3, C4, U&E, LFTS, HB but abnormal WCC 18.4 (nr<4) Neut 14.14 (nr<7), Eosinophils 0.75, Globulins 39.8 (nr<30), CRP 105.4, ESR 52 and positive ANCA (atypical P-ANCA) PR3 positive,

titre 6.4 (nr<3) and MPO negative, Urinalysis was normal. CT scan of brain, thorax, abdomen and pelvis was normal. CT sinuses showed findings consistent with moderate to severe sinusitis involving maxillary and ethmoid sinuses. It also showed severe destruction of the nasal septum anteriorly and the mid-section with some preservation posteriorly. Nasal biopsy of the left middle turbinate, inferior left turbinate, left superior turbinate, septum and left nasal vestibule shows inflamed granulation tissue with eosinophils in most of these biopsies. No evidence of dysplasia, malignancy. No evidence of granuloma. History of Cocaine usage noted by GP previously and patient admitted to having used Cocaine frequently. Urine Toxicology screen was also noted positive for Cocaine at one occasion at GP in February 2019. Patient was explained his diagnosis of Cocaine induced nasal cartilage destruction and ANCA positivity and that only treatment is cessation of Cocaine administration.

Cocaine induced midline destruction and ANCA positive vasculitis has been previously reported in number of case studies. There is known association between the ingestion of levamisole-contaminated cocaine and ANCA-associated systemic autoimmune disease. Further details will be discussed.

(19A190) ABSTRACT 79

CASE POSTER 71

### Psoriatic Arthritis and Tuberculosis – A Perfect Storm

#### Author(s)

Claire Masih Sarah Black Cathy Donaghy Gary Wright

#### Department(s)/Institutions

Musgrave Park Hospital, Belfast

#### Introduction

A 31yr man presented with severe psoriatic arthritis which remained uncontrolled by methotrexate and prednisolone 10mg daily. He commenced Humira May 2018 and his arthritis responded well. Standard pre-biologics investigations included normal chest Xray and IGRA test.

#### Aims/Background

He was admitted with a systemic febrile illness November 2018 and investigations revealed ascites, pleural effusions, abdominal lymph nodes and omental lesions. Humira was stopped and he was initially treated with antibiotics and increased doses of steroids. Omental biopsy was performed and microscopy was suspicious for Mycobacterium tuberculosis. PCR and subsequent culture were positive.

#### Method

Further questioning could identify no risk factors for tuberculosis in terms of lifestyle or exposure except anti-TNF treatment. He commenced standard anti-tuberculosis treatment with Voractiv with a plan to maintain his arthritis with prednisolone during 6 months of tuberculosis treatment. Unfortunately his arthritis deteriorated significantly with the commencement of anti-tuberculosis treatment despite increasing prednisolone dose to 30mg, presumably due to interaction between rifampicin and prednisolone. He required 3 admissions for uncontrolled arthritis during the course of treatment and responded poorly to intramuscular and intravenous steroid preparations but did respond to some degree to joint injections.

#### Results

We plan to commence secukinumab/Cosentyx when his TB treatment is complete.

#### Conclusions

We present this case to raise awareness of primary non-pulmonary tuberculosis in a young patient with no risk factors besides anti-TNF treatment. The interaction between rifampicin for tuberculosis treatment and prednisolone has caused particular difficulties controlling this patient's arthritis throughout his tuberculosis treatment.



Photos from ISR Spring Meeting 2019



Dr Dalal Alkhudir, Dr Ahmed Al Maqbali, Dr Shamma Alnokhatha and Dr Yousef Alammari



Dr Len Harty, Dr Laura Durcan, Dr Miriam O'Sullivan and Professor Andrea Kalus



Photos from ISR Spring Meeting 2019



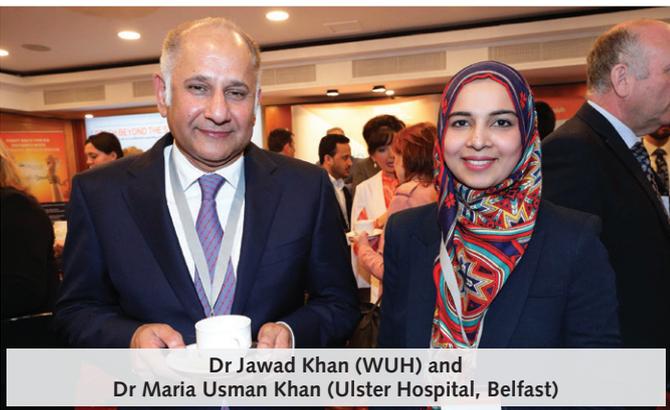
Dr Fahd Adeb (Tralee), Ms Ann O’Riordan (Tralee); Mr David McCan (AbbVie) and Dr Shehla Farrukh (Tralee)



Ms Tracey Kivlehan (Accord) and Ms Martina Fitzpatrick (SVUH)



Ms Anna Barrett (Accord) and Dr Caitriona Buckley (Bons Secours Tralee)



Dr Jawad Khan (WUH) and Dr Maria Usman Khan (Ulster Hospital, Belfast)



Ms Claire Madigan (Janssen) and Ms Patricia Minnock (Hospice Harold’s Cross)



Photos from ISR Spring Meeting 2019



Dr Sinead Harney and Professor Geraldine McCarthy



Ms Patricia Kavanagh (MMUH), Mr Michael Dineen (ISR);  
Ms Martina Cooney (Hospice Harold's Cross)  
and Ms Dorcas Mafava (Hospice Harold's Cross)



Dr Peter Browne (Bons Secours Tralee), Dr Lorraine O'Neill (Oxford)  
and Dr John Jackman (Oxford)



Dr Frances Stafford (Blackrock Clinic) and Mr Ollie Kinlough (AbbVie)



Mr Brian Whately (Novartis) and Prof Anne Barbara Mongey (SVUH)



## IRHPS Speakers

### Karen Quinn

Physiotherapy Department, Cork University Hospital

### Dr. Louise Larkin

School of Allied Health, Faculty of Education & Health Sciences,  
University of Limerick

### Helen Reynolds

North Western Rheumatology Unit,  
Our Lady's Hospital, Manorhamilton,  
Co. Leitrim

### Gráinne O'Leary

Chief Executive Arthritis Ireland



Gráinne O'Leary is Chief Executive of Arthritis Ireland where she is leading the strategy of the charity to be one of the leading patient centric medical research charities in Ireland.

Before becoming Chief Executive in January 2018, Gráinne developed and implemented Arthritis Ireland's suite of patient support services, including the innovative Stanford University self-management programme, a national helpline and a national physical activity programme in partnership with the Irish Society for Chartered Physiotherapists.

She has developed key relationships across the healthcare arena, including with corporate partners and funders, healthcare professionals, the HSE and related agencies, professional bodies, academia, government officials and other patient groups.

She serves as a Board member of the Disability Federation of Ireland and IPPOSI.

### Professor Will Dixon

Director of the Arthritis Research UK Centre of Epidemiology,  
Medical Director of Greater Manchester Connected Health Cities,  
Honorary Consultant Rheumatologist,  
Salford NHS



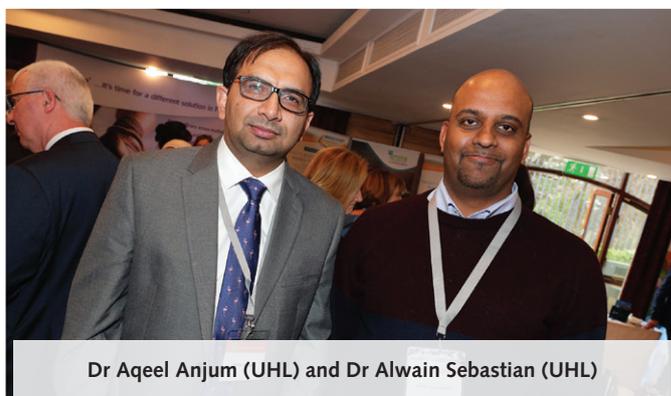
Will Dixon qualified from Guy's and St. Thomas' Hospitals, London, trained as a rheumatologist in Manchester, UK and has higher degrees from The University of Manchester and McGill University, Montreal. He is a Professor of Digital Epidemiology, Director of the Centre for Epidemiology Versus Arthritis at the University of Manchester and an honorary consultant rheumatologist at Salford Royal NHS Foundation Trust.

His passion is using technology to support clinical care and research to improve patients' lives. This includes the collection and sharing of research quality data from clinicians, collecting patient-generated data including its integration into electronic health records, and analysis of social media data. Recent digital health studies include the national smartphone study and citizen science experiment Cloudy with a Chance of Pain, a study of remote monitoring in rheumatoid arthritis (REMORA) which uniquely integrates patient-generated data into the NHS, and Koalap, the world's first cellular smartwatch health research study.

## Photos from ISR Spring Meeting 2019



Mr Gerard D'Arcy (Roche); Ms Ann O'Riordan (Tralee)  
Mr Gerard Walsh (Roche) and Claire Lenihan (Roche)



Dr Aqeel Anjum (UHL) and Dr Alwain Sebastian (UHL)



## ABSTRACT 1

### The relationship between pain and sedentary behaviour in Rheumatoid Arthritis

#### Authors:

Karen Quinn(1), Louise Larkin(2), Grainne Murphy(3), Helen O Leary(4).

#### Department(s)/Institution(s):

(1) Physiotherapy Department, Cork University Hospital; (2) School of Allied Health and Health Research Institute, University of Limerick; (3) Rheumatology Department Cork University Hospital; (4) Physiotherapy Department, University Hospital Kerry.

#### Aim/Introduction:

Sedentary behaviour (SB) is associated with increased cardiovascular risk in people with rheumatoid arthritis (RA) independent of physical activity levels.<sup>1</sup>

This study aimed (i) to quantify subjectively and objectively measured SB in a cohort of Irish people with RA, and (ii) to determine the associations between objectively measured SB and clinical factors.

Method: People with RA were recruited from a rheumatology clinic. SB was measured objectively over a 7-day period using the Activ4PAL accelerometer. Information about pain symptoms, fatigue, mood, sleep quality and subjective report of sedentary time were recorded using validated questionnaires. Disease activity was measured using the Clinical Disease Activity Index (CDAI).

Results: Participants with valid accelerometer data (n=72) spent an average of 8.9 hours (SD 1.6) per day in SB. Participants' mean subjective estimate of their sedentary time was 5.2 hours (SD 2.2). Significant positive associations with daily sedentary time were found for pain intensity ( $r = 0.31$ ,  $p < 0.01$ ) and number of painful joints ( $r = 0.24$ ,  $p < 0.05$ ). SB was higher in those reporting foot and ankle pain ( $p < 0.05$ ). However in multivariable analyses these pain characteristics were not independently associated with SB. Other correlates of daily sedentary time included anxiety and depression but not fatigue or sleep.

#### Conclusion:

Participants spent a significant proportion of waking hours engaged in sedentary activities and tended to underestimate this time. Results suggest that self-report pain intensity, depression and foot pain are related to volume of SB. However after accounting for demographics and disease activity these relationships did not maintain significance. Further research should explore other factors beyond the symptoms of RA that may influence SB.

#### References:

Fenton SAM, Veldhuijzen van Zanten JJCS, Kitas GD, Duda JL, Rouse PC, Yu C an, et al. Sedentary behaviour is associated with increased long-term cardiovascular risk in patients with rheumatoid arthritis independently of moderate-to-vigorous physical activity. *BMC Musculoskelet Disord* 2017;18:1–12

## ABSTRACT 2

### Factors affecting completion rates of physical activity interventions in people who have rheumatoid arthritis: a systematic review

#### Author(s):

Niamh Renyolds<sup>1</sup>, Louise Larkin<sup>1,2</sup>

#### Department(s)/Institution(s):

<sup>1</sup>School of Allied Health, Faculty of Education & Health Sciences, University of Limerick

<sup>2</sup>Health Research Institute, Faculty of Education & Health Sciences, University of Limerick

#### Aim/Introduction:

Rheumatoid arthritis (RA) is an inflammatory condition which

impacts health outcomes. Physical activity (PA) has numerous health benefits, including reduction of symptom severity and risk of cardiovascular disease<sup>1</sup>. However, people with RA do not meet PA recommendations<sup>2</sup>. The aim of this systematic review was to determine the factors which affect completion of PA interventions in RA.

#### Method:

A systematic review of the literature was conducted. Searched databases included Ebsco, Pubmed and Web of Science. Quality of included papers were assessed using the Cochrane risk of bias tool by two assessors. Data was extracted and analysed using basic descriptive statistics.

#### Results:

Twelve studies with 1454 participants were included. Included studies were of varying levels of quality. Eleven studies had high completion rates (375% completion rate). One study<sup>3</sup>, which used a website-based intervention, had lower completion rates (55% completion rate). Interventions varied in frequency, intensity and type of exercise, and included aerobic, resistance and flexibility exercise. Interventions which incorporated behaviour change techniques increased completion rates. Reported adverse outcomes included an increase in pain as a result of the intervention. Altering the intervention in response to adverse outcomes improved completion rates of the intervention.

#### Conclusion:

Interventions which utilise aerobic and resistance activities are associated with high completion rates in RA, meeting the EULAR guidelines for PA<sup>4</sup>. Behaviour change techniques were associated with high completion rates and should be included in interventions targeting PA participation. Adverse outcomes should be reported and modifications made to PA programmes to minimise/avoid these outcomes. Future research and clinical practice should consider our review findings when designing PA interventions for people with RA.

## ABSTRACT 3

### A Descriptive Account of the Practices of Rheumatology Nurses in the Provision of Telephone Helpline Services in the Republic of Ireland.

#### Author(s) H. Reynolds.

Department(s)/Institution(s): North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co. Leitrim

#### Aim/Introduction:

The provision of telephone advice is an integral component of the nurses' role in the delivery of health care to patients with rheumatic conditions and is recommended in the literature (EULAR 2018, RCN 2012, BSPAR 2010). There is a paucity of literature in the Irish setting. This study examined the practices of rheumatology specialist and advanced practice nurses in the provision of telephone helpline services in the Republic of Ireland.

#### Method:

This study was conducted in part fulfilment of a Master's of Science in Nursing Advanced Practice. Data were collected in February 2019 using purposive sampling and an on-line questionnaire. Information collected included characteristics of the respondents, their rheumatology services and telephone helpline services.

Results: Fifty questionnaires were distributed; a response rate of 82% (n = 41) was achieved with representation from all hospital groups. 83% of rheumatology centres provide a nurse-led telephone helpline service with evidence of similarities and variations in service provision. A significant amount of time is spent providing this service with 40% (n = 15) reporting they spend 41% - 60% of their day providing telephone advice. Time-constraints and governance issues were highlighted. From a cost-effective perspective, the respondents were of the opinion that this service reduces the need for face to face



consultation in both the hospital and primary care settings.

**Conclusion:**

Telephone helplines are widely utilised across all rheumatology centres nationally. However, in order for the full potential of this service to be achieved and recognised an in-depth evaluation in terms of efficacy, cost effectiveness and governance is warranted. In the current climate of increasing demands and diminished resources this key aspect of healthcare delivery should be maximised.

**ABSTRACT 4**

**Development of a Methotrexate Digital Media Card and dedicated Methotrexate website**

**Author(s):**

Una Martin **Department(s)/Institution(s):**

University Hospital Waterford

**Aim/Introduction:**

Methotrexate (MTX) remains the standard treatment for inflammatory arthritis. For patients prescribed MTX they tell us they find it difficult to source correct information about MTX. They require this information at different time points in their disease and in different formats that encompass literacy and language challenges.

**Method:**

Following on from the development of the MTX patient education guide and in partnership with a digital media company the content was converted into a 3 minute digital animation with audio. This is available in a digital media card or through www.methotrexate.ie. The website and digital media card was launched nationally in September 2019 with the support of the IRNF and Arthritis Ireland. The website is advertised nationally through Arthritis Ireland and all patients prescribed MTX are given the website details as part of their education programme.

**Results:**

Since launch in September 2018 there has been 1.2k sessions, 928 new users and 98 returning visitors. The website has been accessed globally, with over 930 visits from Ireland, 86 (United States) & 23 (UK). The website is accessed by mobile (59.86%), desktop (32.62%) & tablet (7.5%). The digital media card is now used nationally in rheumatology centres when educating patients formally about MTX. **Conclusion:** To date the website continues to be accessed by patients and we have received very positive feedback from both patients and staff using both the website and the digital media card. The next step is to survey the users and identify what additions that may enhance the website.

**ABSTRACT 5**

**Using the RA PREM to evaluate the patients experience following the implementation of an RANP at UHW**

**Author(s):**

Una Martin

**Department(s)/Institution(s):**

University Hospital Waterford

**Aim/Introduction:**

Capturing the patients views on quality service is fundamental following the implementation of a new service. The DoH is collecting data from candidate ANP's & ANP's pertinent to reducing waiting lists and avoiding hospital admissions. Recording patients experience has the potential to improve quality of care. The RANP at UHW was appointed in June 2019 and is responsible for a caseload of patients with IA, with unstable disease defined by certain criteria.

**Method:**

Patients that had been referred to the RANP and had attended at least 1 clinic appointment were asked to complete the RA PREM (Bosworth et al 2015). The RA PREM tool was used to measure the patients experience of the RANP clinic. It was modified to incorporate the RANP specifically. The survey was conducted via a postal questionnaire.

**Results:** A total of 70 patients were sent the questionnaire, 55 were returned. The Demographics are shown in Table 1. The responses for the PREM from each domain important to the patient experience are shown in Table 2.

**Conclusion:**

The results of the survey demonstrate that patients had a good experience with the RANP service. However the number of visits with the RANP was not recorded. The results may not all be attributable to the RANP as caseload has the input from an MDT. The survey demonstrated that 67% of patients over the last year had a good experience of care for their inflammatory arthritis. One of the areas within the service that requires review and further input is the provision of patient support groups.

Table 1: Demographics

Demographics				
<b>Gender</b>	Males = 19 (34.5%)	Females= 36 (65.45%)		
<b>Duration of Disease</b>	Less than 2 years= 19 (34.53%)	Between 2 to 5 years= 17 (30.9%)	Between 6 and 10 years =16.36 (9)	More than 10 years 10 (18.8)
<b>Age</b>	Aged 30 to 40 = 8 (14.8%)	41 to 50 = 11 (20.3%)	51 to 60 = 15 (27.78%)	61 to 70 = 15 (27.78%) Over 70 = 5 (9.26%)
<b>Educational Status</b>	Primary = 7 (12.73%)	Secondary = 28 (50.91%)	Third Level = 14 (25.45%)	Prefer not to say = 6 (10.9%)



Table 2: Responses for PREM by Domain

Domain	Question (Number of responders )	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1. Needs and Preferences	Treated respectfully as an individual (n=55)	76.36%	23.64%			
	Involved in decisions about care and treatment (n=55)	69.09%	29.09%	1.82%		
	Personal Circumstances and preferences considered (n=55)	72.73%	25.45%	1.82%		
	Given understandable information (n=55)	76.36%	21.82%	1.82%		
	Given enough information (n=54)	59.20%	37.04%	1.85%	1.85%	
2. Coordination of Care	Made aware of health team looking after me (n=55)	67.27%	32.73%			
	Able to access different health team members (n=55)	65.45%	27.27%	7.27%		
	Member of health team helps me access specialists (n=54)	64.85%	25.93%	7.41%	1.85%	
	RANP up to date with my situation (55)	87.27%	12.73%			
	<b>RANP careful to check everything when examining and seeing me (n=45)</b>	86.70%	13.30%			
3. Information about care	Given information at the time I needed (n=55)	63.64%	34.53%	1.82%		
	Good understanding of the treatments I am on or offered (n=55)	54.55%	41.82%	1.82%	1.82%	
	Been told about patient groups /organisations (n=55)	43.64%	32.73%	9.09%	12.73%	1.82%
	<b>Better understanding of my condition after seeing RANP (n=55)</b>	69.09%	23.64%	3.64%	3.64%	
4. Daily living	IA controlled enough to get on with daily life/usual activities (n=55)	38.80%	38.18%	20%	3.64%	
	Able to get help quickly if I have a flare	46.30%	38.89%	9.26%	5.26%	
5. Emotional support	Feel able to approach the RANP to discuss worries about treatment or their affect on my life (n=55)	80.40%	18.18%	1.82%		
	Feel able to discuss personal/intimate issues with the RANP (n=55)	65.46%	23.64%	9.09%	1.82%	
	<b>I thought the RANP took notice of me as a person (n=44)</b>	84.40%	13.30%	2.20%		
6. Family and Friends	Feel able to take family members to appointments /become involved in decisions about my care (n=54)	62.96%	24.07%	11.11%	1.85%	
7. Access to care	Enough time with the RANP to cover everything I want to discuss. (n=54)	79.63%	16.67%	1.85%	1.85%	
	I have had appointments cancelled unexpectedly (n=43)	16.20%			83.70%	
	I have needed to seek help for extra treatment or a change of treatment (n=47)	16.20%			83.71%	
8. Overall Experience	Had a good experience of IA in the last year(n=55)	67.27%	25.45%	3.64%	3.64%	
	<b>Totally satisfied with my visit to the RANP (n=44)</b>	88.64%	9.09%		2.77%	



## ABSTRACT 6

### Establishing a Nurse led Gout Clinic

#### Author(s):

Madeline O'Neill, Patricia Minnock, Dr Imran Ali, Prof Eamonn Molloy, Prof Doug Veale

#### Department(s)/Institution(s):

Our Lady's Hospice and Care Services, Rheumatic Musculoskeletal Diseases Unit, Harold's Cross, Dublin 6W

#### Aim/Introduction:

1. To establish a Registered Advanced Nurse Practitioner (RANP) led gout clinic
2. To provide patients with individualised information and engage them with a treat-to-target urate lowering strategy

#### Method:

1. Consensus agreement to initiate a RANP led clinic was reached with key stakeholders
2. Appropriate documentation was developed inclusive of defined referral pathways, inclusion/exclusion criteria for referral to the clinic and audit tools (proforma/questionnaire)
3. An audit was designed to evaluate numbers of referrals and reasons for referrals on a monthly basis to inform appropriate service development

#### Results

- Since inception in April 2019:
- 39 patients have been removed from the hospital waiting list
- 37 patients have been referred to the RANP led gout clinic. Their care continues within this RANP service
- 2 patients have been discharged back to general practitioner care

#### Conclusion:

##### Plan for Sustainability

- Ongoing audit and evaluation of the impact of the RANP led service to guide this patient centred development which is aligned to the "Slaintecare strategy", the "Quality and Fairness - Irish Health strategy", the "Primary Care strategy" and the recently launched "Model of Care for Rheumatology in Ireland"
- Explore the feasibility of a study of outreach services and education of our community partners to enhance community services
- Aim to extend this project to ANPs in rheumatology nationally in order to provide patients with the right service, in the right place, at the right time

## ABSTRACT 7

### Depression across chronic illnesses.

#### Author(s):

Rachel Kenny

#### Department(s)/Institution(s):

Rheumatology dept. Naas General Hospital/ Tallaght University Hospital

#### Aim/Introduction:

The aim of this study is to investigate the occurrence of depression among patients with chronic illness. It is already known that there is a two to three fold increase in the instance of depression among patients with chronic illness. It is sought to investigate if multiple comorbidities gives rise to a greater occurrence of depression. This study is being undertaken to develop support services patients for patients attending Naas General Hospital with chronic illness that may be shared among nurse led clinics. This study is also the first collaborative nurse research project undertaken in NGH across four

chronic illness areas.

#### Method:

Every third patient seen by the ANPc was invited to participate in the chronic illness and depression study. Demographic data, lifestyle information, DAS 28, along with primary and secondary diagnosis were recorded following consent. Data collected was exported to SPSS and compared narratively and inferentially. Data collection is ongoing, it is aimed to recruit 40 participants from each speciality; rheumatology cardiology, respiratory and dermatology (n=160)

#### Results:

Data to date suggests that patients with multiple comorbidities are more likely to express depressive symptoms. Most participants do not have a formal diagnosis. Participants whom are in the early stage of diagnosis and treatment of their rheumatological condition (<2yrs) express depressive symptoms more frequently than those farther along in treatment.

#### Conclusion:

Depression is a common feature among patients whom have received a new rheumatology diagnosis which is not always acknowledged. Patients identify symptoms of depression and are forthcoming with symptoms. Referral options are limited for participants requiring referral to counselling or psychology services.

## ABSTRACT 8

### Candidate Advanced Nurse Practitioner delivered Inflammatory Arthritis Stable Review Clinics at Tallaght University Hospital. Preliminary audit of Patient Profile and Clinical Outcomes.

#### Author(s):

Stephanie Naramore, Rachel Kenny, Ronan Mullan, David Kane.

#### Department(s)/Institution(s):

Tallaght Hospital

#### Introduction:

The two candidate Advanced Nurse Practitioners (cANPs) are presently running 7 Stable Review Inflammatory Arthritis (low disease activity /remission) Clinics per week alongside the Rheumatology Medical Clinics in Tallaght University Hospital. Aim: To explore and establish if the patients booked to the CANP Stable Review Clinics are appropriately referred.

Method: An audit of the patients seen over a four week period was performed. Data collected looked at whether patients referred to the cANP Stable Review Clinics were appropriately referred, and to document what interventions and referrals were carried out at the clinic.

#### Results:

84 patients were seen by the cANPs over a 4 week period. 50 Rheumatoid Arthritis, 15 Psoriatic Arthritis, 7 Ankylosing Spondylitis, 6 undifferentiated Inflammatory Arthritis. 8 did not meet referral criteria (Osteoarthritis, Polymyalgia Rheumatica and Scleroderma).

Interventions at clinic comprised of;

- 20 synthetic/biologic DMARD changes including escalation / de-escalation/switches of medications
- 11 intramuscular Depomedrone injections
- 17 x-rays referrals
- 10 u/s guided injection referrals.
- 9 MDT referrals
- 5 orthopaedic referrals

#### Conclusion:

Patients scheduled to the Stable Review Clinics were largely appropriate (90% inflammatory arthritis) for further CANP



management with a small number (10%) of referrals outside the scope of referral criteria. Stable review clinics are responsive to the continuing care needs of patients with Inflammatory Arthritis. There may be consideration of increasing the scope of the CANP in the future.

#### ABSTRACT 9

### A randomised controlled clinical trial comparing the effectiveness of 6 and 12 weeks of a shoulder specific exercise programme for a shoulder specific exercise programme for patients with rotator cuff related shoulder pain

#### Author(s):

Sandra Keyes, Noreen Walsh, Mark Phelan

#### Department(s)/Institution(s):

Physiotherapy Department, South Infirmity Victoria University Hospital, Cork; Department of Rheumatology, South Infirmity Victoria University Hospital, Cork

#### Aim/Introduction:

To determine if 6 weeks of a supervised shoulder specific exercise programme is as effective as 12 weeks of the same programme, for improving shoulder function, self-reported disability and pain, in patients with rotator cuff related shoulder pain.

#### Method:

Patients with a history of lateral upper arm pain with MRI confirmation of rotator cuff pathology or positive testing on a cluster of clinical rotator cuff tests were included in the study. Patients with a recent history of shoulder surgery or a shoulder fracture were excluded. Participants were randomly assigned to complete either 6 weeks (short group) or 12 weeks (long group) of the same exercise programme. Participants were assessed using the Constant-Murley (CM) score, the QuickDash, the Shoulder Pain and Disability Index (SPADI) and a visual analogue scale for pain. Group comparisons were made using univariate generalised linear models.

Results: 85 patients were included in this study as per Table 1.

Table 1

Characteristics	Short (n = 45)	Long (n = 40)
Sex (male/female)	24/21	21/19
Age in years median (SD)	57 (15)	57 (14)
Duration of symptoms (median months)	19	24

Within each group all outcomes improved significantly at 3 months ( $p < .05$ ). Comparisons at 3 months showed the long group had significantly lower pain scores ( $p = .02$ ). At 6 months, the long group had significantly greater changes in the CM score ( $p = .007$ ) and the SPADI score ( $p = .002$ ).

#### Conclusion:

In patients with rotator cuff related shoulder pain a 12 week exercise programme results in better outcomes for pain at 3 months and self-disability and shoulder function at 6 months.

#### ABSTRACT 10

### Addressing the Rheumatology CNS waiting list in MRHT

#### Author(s):

Eileen Shinnors, Angela Camon, Dr Ausaf Mohammad, Dr Killian O'Rourke

#### Department(s)/Institution(s):

Dept of Rheumatology, MRHT, Tullamore Co Offaly

#### Introduction:

Rheumatology provides approx 2,500 outpatient appointments annually. Following the cANP appointment (October 2017), the CNS waiting list grew due to delays (>1 year) backfilling the CNS post. When the CNS began in January 2019, reduction of the CNS waiting list was prioritised.

#### Method:

The waiting list audit identified referral reason; waiting times; those discharged from clinic/ seen by the CNS already, or who have DNA'd CNS appointments previously. Electronic records were reviewed for diagnosis, prescribed treatment and date of next medical appointment. Two concurrent workstreams were initiated- the first offered appointments to those waiting longest regardless of their next appointment date. The second workstream identified patients attending imminent medical review to see the CNS the same day. All patients were contacted by phone to confirm appointments.

During a 1 hour appointment, understanding of the diagnosis was assessed; rheumatology patient reported outcome measures (PROMs) were completed; medication reconciliation was conducted, and lifestyle issues discussed. Any identified knowledge gaps were addressed with verbal/ written information.

#### Results:

121 patients waited on average 116.25 weeks to see the CNS. Referral reason included patient education/ health promotion, PROMs and review of treatment response. In 20 weeks (mid-March to end July 2019), 8 patients removed from waiting list (seen already), 14 patients removed (patients discharged from clinic) and 48 patients were offered appointments to date. 6 DNA'd their appointments and 42 patients were seen.

#### Conclusion:

The Rheumatology CNS role is recognised as essential to the provision of safe, effective quality patient care (EULAR, 2012; HSE 2018). Within Rheumatology MRHT, the CNS waiting list was halved in 5 months with the goal to see all patients before year end.

#### ABSTRACT 11

### The role of the candidate ANP in leading implementation of change potentially improving outcomes relating to osteoporosis risk assessment. This is identified through implementation science and using the Consolidated Framework for Implementation Research (CFIR).

#### Author(s):

Martina Carolan

#### Department(s)/Institution(s):

Rheumatology Department, Our Lady's Hospital, Navan, Co. Meath

#### Aim/Introduction:

Clinical Practice Guidelines (CPG) could decrease the gap between evidence based research and current practice, yet implementation remains inconsistent. This study, addressing a quality gap, explored implementation of CPG for risk assessment of osteoporosis. A



process evaluation sought to identify barriers/facilitators affecting implementation, and strategies utilised, as identified by the Expert Recommendations for Implementing Change (ERIC) (Powell et al., 2015) to achieve an implementation outcome of acceptability (Proctor et al., 2011).

**Method:**

Implementation science was used with the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) guiding and enabling comprehensive systematic evaluation of data. Formative evaluation accompanied by an adapted ratings scale identified influences on implementation during this early stage study. Emergences of key themes were linked to the domains and constructs of CFIR.

**Results:**

The emergent key themes were - (1) role of audit and feedback in creating tension for change and acknowledging relative priority to address patient needs. (2) The evidence strength and quality of the guidelines adapted for use, proved facilitative in achieving acceptability. (3) Compatibility was attained through extension of current candidate Advanced Nurse Practitioner (cANP) led care. (4) The role of the cANP as a middle manager with individual characteristics of self-efficacy and capability emerged as key, in leading and facilitating change. (5) Networks and communications proved critical in understanding, knowledge sharing and development of interdepartmental relationships beneficial to implementation.

**Conclusion:**

This study identifies methodology and frameworks regarding implementation and contributing to understanding acceptability as an implementation outcome.

It highlights the role of the cANP as a middle manager in developing the capacity to lead implementation of change, potentially improving patient and service outcomes.

**ABSTRACT 12**

**7 year Audit of Nurse Led Rheumatology IV Infusion Service provided at the Midland Regional Hospital Tullamore**

**Author(s):**

Eileen Shinnars, Angela Camon, Dr Ausaf Mohammad, Dr Killian O'Rourke

**Department(s)/Institution(s):**

Rheumatology Dept, Midland Regional Hospital Tullamore (MRHT)

**Aim:**

To conduct a review of all IV Infusions administered in the Rheumatology Infusion Suite MRHT since inception in September 2012, including service development, medications administered, cost of treatment, patient safety and patient satisfaction.

Method: A retrospective audit of infusions given since June 2012 was conducted. Dept records were reviewed, service expansion was discussed (including procuring dedicated infusion space, creation of evidence based protocols, development of nurse-led service). On supply, pharmacy provides cost of medications enabling data collection. Review of patient safety issues was conducted and patients were given short satisfaction questionnaire to complete.

**Results:**

Following ongoing issues securing bed space, the Rheumatology Infusion Suite was developed in June 2012. Departmental PPPGs were developed and reviewed using a multidisciplinary approach, supporting best practice. Mean infusions administered monthly (4.65- August 2012- June 2019) by one nurse. Due to service demand, in June 2018 a second nurse was added max 2 days/ week (due to particular requirement for IV Privagen) and mean monthly

infusion number increased to 9.92. Patient safety data indicates no cannulation-related infections, and patients have better disease control with regular infusions. Patients receiving infusions had reduced A&E/ inpatient admissions once stable on treatment and patient satisfaction with the service is excellent.

**Conclusion:**

While patient self-management with their medication is advocated in chronic diseases including rheumatic disease, certain patients benefit from regular IV therapy to control their disease. Audit of IV therapies given in the Infusion Suite, MRHT over a 7 year period has demonstrated service improvements over time, consistent patient safety, and high patient satisfaction. Regular review of this patient group has allowed for additional benefits including joint injections as required.

**ABSTRACT 13**

**Cost Savings Switching from Intravenous (IV) to Subcutaneous (SC) Tocilizumab in the Irish National Centre for Paediatric Rheumatology**

**Author(s):**

C Lang1 JM MacMahon2, K Peate2, E MacDermott2, OG Killeen2  
Department(s)/Institution(s):

1. Pharmacy Department, Children's Health Ireland at Crumlin, Ireland.
2. National Centre Paediatric Rheumatology, Children's Health Ireland at Crumlin, Ireland.

**Aim/Introduction:**

Subcutaneous (SC) tocilizumab (TCZ) has become a valuable alternative to intravenous (IV) administration in patients with juvenile idiopathic arthritis (JIA). Although the pharmacokinetic profiles of both formulations differ, SC TCZ has locally demonstrated to be as effective, safe and well-tolerated as IV TCZ.1 The purpose of this study was to review the differences between SC and IV TCZ from a health-economic perspective, in the first 6 months after SC TCZ was licensed for JIA.

**Method:**

Retrospective comparative review of TCZ JIA patients from October 2017 to April 2018 in comparison to the same period in 2018/19 since the introduction of SC TCZ. Patients on TCZ were identified from an in-house pharmacy database. Patients on TCZ for indications other than JIA were excluded. Drug expenditure was identified from Cliniscript® reports and number of patient episodes for IV TCZ hospital reports.

**Results:**

IV TCZ patient numbers reduced by 46% by April 2019 in comparison to 2018. Of the eligible patients with JIA, 10/20 (50%) switched to SC TCZ. All new JIA patients 10/10 (100%) who required treatment with TCZ since October 2018 were initiated on SC. Patient episodes for IV TCZ on the medical day unit (MDU) reduced from 190 to 130, a reduction of 32% between October to April 17/18 compared to 18/19.

TCZ drug expenditure was reduced by over 40%.



#### ABSTRACT 14

### Benefits of the Expanded Role of A Clinical Nurse Manager 1 (CNM1) in Pre-Admission Assessment for Day and In-Patients, in a Rheumatic & Musculo-Skeletal Disease Unit (RMDU).

#### Author(s):

Martina Cooney, RGN, BScHons, Grad-Dip Rheumatology.

#### Department(s)/Institution(s):

Rheumatic & Musculoskeletal Disease Unit (RMDU), Our Lady's Hospice & Care Services (OLH&CS), Harolds Cross, Dublin 6W

#### Aim/Introduction:

The RMDU at OLH & CS is a unique service admitting over 800 in-patient and day-patients annually for rheumatology rehabilitation (3) A multi-disciplinary admissions committee was formed in August 2013 to clinically triage and grade the referral forms.(2) Omitted or additional information from referral source or patient was often required. Service could improve if a clinical coordinator managed queries, whilst enhancing communication and the patients' journey. Funding became available for 65 hours over a six week period and the Expanded Role of the CNM1 was agreed and formed.

#### Method:

A pre-admission assessment telephone call was made to select new and some returning patients using a tool the CNM1 designed (1). Criteria to call the patient were based on missing information from referral form \*

#### Results:

CNM1 made telephone calls to 44.7% of the 105 patient referrals received over the 6 week period:

58 no phone call required as satisfactory information on referral form.

47 pre-admission assessment phone calls:

- 2 deferred admission dates due to being unwell
- 4 had MDT assessment
  - 3 deemed unsuitable as had no rehabilitation goals
  - 1 deemed suitable after MDT assessment

42 added to waiting list for admission

#### Conclusion:

Patients reported satisfaction with phone-call and expressed better understanding for admission reasons to RMDU. Admissions officer very supported regarding clinical issues. Communication greatly improved. Effective use of MDT resources achieved through assessment for select patients only. In the future, the author proposes to integrate the expanded CNM1 role into current CNM1 remit; to gather patient reported outcome measures (PROM's); audit patients' experience and ability to self-manage; to adapt assessment tool to encompass MDT as a whole and explore a discharge coordination piece in conjunction with the pre-admission assessment role.

#### ABSTRACT 15

### Establishing an Occupational Therapy (OT) pathway for the conservative management of Carpal Tunnel Syndrome (CTS).

#### Author(s):

Minchin, Paula & Rafferty, Carol; Senior Occupational Therapists.

#### Department(s)/Institution(s):

OT Department, Tallaght University Hospital, D24

#### Aim/Introduction:

Referrals to OT for conservative management of CTS are received from Rheumatology, Orthopaedic and Neurology teams. Treatment

provided, varied between clinical areas within OT. A waiting list of 103 patients, waiting 22 months had developed. It was suspected that this delay increased the chronicity of symptoms and failed to maximise outcomes of conservative management. By updating the treatment protocol and introducing new methods of service delivery, we aimed to clear the waiting list, ensure equity and best practice, while maximising time efficiency.

#### Method:

Six months funding for 2x 0.25WTE Senior OT's was awarded by the Meath Foundation to manage this backlog. Communication with Neurophysiology, Physiotherapy and our referrers informed the project plan. A literature review was completed, focused on current evidence supporting conservative management, group education and outcome measures (OCM). Subsequently, a group education presentation was written, addressing self-management of CTS, exercise and splinting. A new clinical pathway was developed (Fig.1) including the Stothard OCM, Boston CTS questionnaire, subjective outcome and patient satisfaction questionnaires. Proformas were designed for patient assessments, subjective outcomes, and discharge reports.

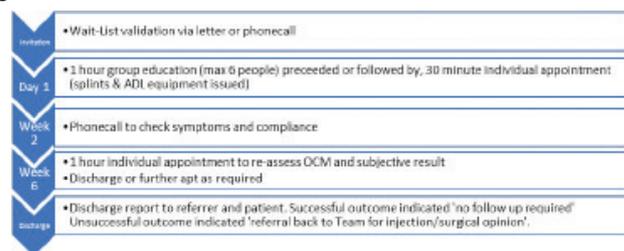
#### Results:

The waiting list has been cleared and clinical outcomes will be published shortly. A new pathway for CTS management has been established and will be rolled out to OT staff. This is supported by a revised clinical guideline, assessment pack, patient information pack and group presentation.

#### Conclusion:

New methods of service delivery, including telephone reviews and group education, has improved the efficiency and quality of service. Development of a standardised pathway has supported equity for all CTS patients attending OT. Multi-disciplinary team (MDT) working has been enhanced and a further project is underway to streamline the pathway within the full MDT.

Fig.1



#### ABSTRACT 16

### Evaluation of a Lifestyle Management for Arthritis Group for people with inflammatory and degenerative arthritis

#### Author(s):

Jane Brownlee, Emer Sheridan, Aoife Synnott, Aoife McCormack, Dr. Mary Bell and Professor Oliver Fitzgerald

#### Department(s)/Institution(s):

The Occupational Therapy department, Rheumatic and Musculoskeletal Disease Unit, Our Lady's Hospice & Care Services

#### Aim/Introduction:

Occupational therapy self-management groups aim to assist individuals to incorporate health-promoting behaviours and management strategies into their daily routines to promote wellbeing. The Lifestyle Management for Arthritis Group (LMAG) is a two-hour-long, educational-behavioural group adapted from the evidence-based Lifestyle Management for Arthritis Programme1



and was delivered to inpatients with inflammatory and degenerative arthritis over a 28 week period. The aims of the study were: to evaluate the effectiveness of LMAG in an inpatient Rheumatology Rehabilitation setting and to acquire participant feedback using an evaluative questionnaire and individual interviews.

**Method:**

A mixed-method sequential design comprising two phases was employed including a survey of 47 eligible participants using the "Joint Protection Knowledge Assessment" 2 (JPKA) gathered at three intervals (pre, post and 6 weeks). In-depth semi-structured phone interviews were undertaken six weeks post group. The quantitative data were analysed using IBM SPSS version 25 while content and thematic analysis techniques were used to analyse the interviews.

**Results:**

Of the 47 participants who attended the group, 38 completed the 6 week follow up post-group. 60% (n=32) were over 61 years, 97% (n=46) were female while 58% (n=27) had Inflammatory Arthritis and 41% (n=19) had Degenerative Arthritis. The results from the JPKA after six weeks post group demonstrated a significant statistical effect indicating that the participants had increased and retained the knowledge gained over time. While over two thirds of the participants evaluated the experience as excellent, empowerment emerged as the core concept from the qualitative analysis.

**Conclusion:**

This study advanced the understanding of the long-term beneficial impact of LMAG in empowering patients in an inpatient setting with inflammatory and degenerative arthritis.

Photos from ISR Spring Meeting 2019



Professor Gary Macfarlane, Speaker



Professor Gaye Cunnane



Professor Raashid Luqmani, Speaker



Dr Robert Harrington, Dr Ahmed Al Maqbali and Dr Brona Dinneen



Audience View



Dr Austin O'Carroll, Speaker



## **ISR Meeting Autumn, 2019 Exhibitors**

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**RAPID AND SUSTAINED  
EFFICACY**<sup>1-6</sup>  
A MARK OF XELJANZ

AN ORAL JAK INHIBITOR FOR THE TREATMENT OF RA, PsA AND UC<sup>7</sup>

**XELJANZ<sup>®</sup> (tofacitinib) Prescribing Information:**

Please refer to the Summary of Product Characteristics (SmPC) before prescribing XELJANZ 5 mg or 10 mg film-coated tablets. **Presentation:** Film-coated tablet containing tofacitinib citrate, equivalent to 5 mg or 10 mg tofacitinib. **Indications:** In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. Can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. In combination with MTX for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. **Dosage:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Tofacitinib is given with or without food. **RA and PsA:** The recommended dose is 5 mg administered orally twice daily. **UC:** The recommended dose is 10 mg given orally twice daily for induction for 8 weeks and 5 mg given twice daily for maintenance. For patients who do not achieve adequate therapeutic benefit by week 8, the induction dose of 10 mg twice daily can be extended for an additional 8 weeks (16 weeks total), followed by 5 mg twice daily for maintenance. Tofacitinib induction therapy should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16. For some patients, such as those who have failed prior tumour necrosis factor (TNF) antagonist therapy, consideration should be given to continuation of the 10 mg twice daily dose for maintenance in order to maintain therapeutic benefit (see SmPC section 5.1). Patients who experience a decrease in response on tofacitinib 5 mg twice daily maintenance therapy may benefit from an increase to tofacitinib 10 mg administered twice daily. It is recommended not to initiate dosing in patients with an absolute lymphocyte count (ALC) less than  $0.75 \times 10^9/l$ , an absolute neutrophil count (ANC) less than  $1 \times 10^9/l$  or in patients with haemoglobin less than 9 g/dL. **Renal impairment:** No dose adjustment is required in patients with mild or moderate renal impairment. Patients with severe renal impairment the dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal renal function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose is 10 mg twice daily when the indicated dose in the presence of normal renal function is 10 mg twice daily. Patients with severe renal impairment should remain on a reduced dose even after haemodialysis. **Hepatic impairment:** No dose adjustment is required in patients with mild hepatic impairment. Patients with moderate hepatic impairment dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal hepatic function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal hepatic function is 10 mg twice daily. Tofacitinib should not be used in patients with severe hepatic impairment. **Elderly:** No dose adjustment is required in patients aged 65 years and older. Use with caution as increase risk and severity of adverse events. **Drug-drug Interactions:** Tofacitinib total daily dose should be reduced by half in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g., ketoconazole) and

inpatients receiving 1 or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole). Coadministration of XELJANZ with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response. Coadministration of potent inducers of CYP3A4 with XELJANZ is not recommended. **Contraindications:** Hypersensitivity to any of the ingredients, active tuberculosis (TB), serious infections such as sepsis, or opportunistic infections, severe hepatic impairment, pregnancy and lactation. Tofacitinib 10 mg twice daily is contraindicated in patients who have one or more of the following conditions: use of combined hormonal contraceptives or hormone replacement therapy, heart failure, previous venous thromboembolism, either deep venous thromboembolism or pulmonary embolism, inherited coagulation disorder, malignancy, or patients undergoing major surgery. **Warnings and Precautions:** Tofacitinib should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Patients treated with tofacitinib should be given a patient alert card. There was a higher incidence of adverse events for the combination of tofacitinib with MTX versus tofacitinib as monotherapy in RA clinical studies. Tofacitinib should be avoided in combination with biologics and potent immunosuppressants such as azathioprine, 6-mercaptopurine, ciclosporine and tacrolimus. **Infections:** Serious and sometimes fatal infections have been reported in patients administered tofacitinib. Rheumatoid arthritis patients taking corticosteroids may be predisposed to infection. Patients should be closely monitored for infections, with prompt diagnosis and treatment. Treatment should be interrupted if a serious infection develops. Use carefully in elderly or patients predisposed to, or with a history of infection (e.g. diabetes). **Tuberculosis:** Patients should be evaluated for both active and latent TB prior to being treated with tofacitinib, patients who test positive for latent TB should be treated with standard antimycobacterial therapy before administering tofacitinib. **Viral Reactivation:** In clinical studies viral reactivation and cases of herpes zoster have been observed. Screening for viral hepatitis should be performed in accordance with clinical guidelines prior to starting therapy with tofacitinib. The impact on chronic viral hepatitis is not known. **Vaccinations:** Prior to initiating tofacitinib, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Live vaccines should not be given concurrently with tofacitinib. **Malignancy:** Lymphomas and other malignancies have been observed in patients treated with tofacitinib. Patients with highly active disease may be at higher risk than the general population. The effect of tofacitinib on the development and course of malignancies is not known. NMSCs have been reported, the risk of NMSC may be higher in patients treated with tofacitinib 10 mg twice daily than in patients treated with 5 mg twice daily. Periodic skin examination is recommended in patients at increased risk. **Pulmonary embolism:** Pulmonary embolism has been observed in patients taking tofacitinib in clinical trials and post marketing reports. Tofacitinib 10 mg twice daily is contraindicated in patients who are at high risk for pulmonary embolism (see also SmPC section 4.3). Additional risk factors that should be considered in determining the patient's risk for PE are older age, obesity, smoking status, and immobilisation. **Interstitial lung disease:** Caution is recommended in patients with a history of chronic

lung disease as they may be more prone to infection. Asian patients are known to be at higher risk of ILD caution should be exercised with these patients. **Gastrointestinal perforations:** Tofacitinib should be used with caution in patients who may be at increased risk e.g. diverticulitis or concomitant use of corticosteroids or NSAIDs. **Cardiovascular risk:** Risk factors should be managed as part of usual standard of care. **Hypersensitivity:** Cases of drug hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately. **Laboratory Parameters:** Increased incidence of lymphopenia and neutropenia have been reported and decreases in haemoglobin and should be monitored in accordance with the SmPC. Monitor ANC and haemoglobin at baseline, 4-8 weeks and 3 monthly, ALC at baseline and 3 monthly. Tofacitinib has been associated with increases in lipid parameters maximal effects are observed at 6 weeks. Monitoring should be performed 8 weeks after initiation and managed according to hyperlipidemia guidelines. Increases in liver enzymes greater than 3x ULN were uncommonly reported, use caution when initiating with potential hepatotoxic medicinal products. **Pregnancy & Lactation:** Use of tofacitinib during pregnancy and breast-feeding is contraindicated. **Side Effects:** The most common serious adverse reactions were serious infections; pneumonia, cellulitis, herpes zoster, UTIs, diverticulitis, appendicitis and opportunistic infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension. The most commonly reported adverse reactions in patients receiving tofacitinib 10 mg twice daily in the induction studies were headache, nasopharyngitis, nausea, and arthralgia. Commonly reported adverse reactions ( $\geq 1/100$  to  $< 1/10$ ), were pneumonia, influenza, herpes zoster, urinary tract infection, sinusitis, bronchitis, nasopharyngitis, pharyngitis, anaemia, headache, hypertension, cough, abdominal pain, vomiting, diarrhoea, nausea, gastritis, dyspepsia, rash, arthralgia, pyrexia, oedema peripheral, fatigue, blood creatine phosphokinase increased. Refer to section 4.8 of the SmPC for further information on side effects, including description of selected adverse reactions. **Legal Category:** 51A. **Marketing Authorisation Number:** EU/1/17/1178/003 - 5 mg (56 film-coated tablets); EU/1/17/1178/007 - 10 mg (56 film-coated tablets). **Marketing Authorisation Holder:** Pfizer Europe MA EIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 3531 4676500.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Last revised: 06/2019.

Ref: XJ 7.1.

RA = Rheumatoid Arthritis. UC = Ulcerative Colitis. PsA = Psoriatic Arthritis.

1. Mease P et al. N Engl J Med 2017; 377(16): 1537-1550. 2. Gladman D et al. N Engl J Med 2017; 377(16): 1525-1536. 3. Hanauer S et al. Poster presented at: World Congress of Gastroenterology at the American College of Gastroenterology Annual Scientific Meeting; October 13-18, 2017; Orlando, FL, USA. 4. Sandborn WJ et al. N Engl J Med 2017; 376(18): 1723-1736. 5. Fleischmann R et al. N Engl J Med 2012; 367(6): 495-507. 6. Wollenhaupt J et al. Poster presented at: American College of Rheumatology/ Association of Rheumatology Health Professionals Annual Meeting; November 3-8, 2017; San Diego, USA. 7. XELJANZ Summary of Product Characteristics.



 **Cosentyx<sup>®</sup> reduces the symptoms of PsA and AS and helps improve patients Quality of Life<sup>1-4</sup>**

 **Rapid and sustained improvements in pain and fatigue for your PsA and AS patients through 2 years<sup>5-7</sup>**

 **Sustained efficacy and favourable safety profile established across all indications through 5 years<sup>1,8,9</sup>**

PsA = Psoriatic Arthritis  
AS = Ankylosing Spondylitis



#### ABBREVIATED PRESCRIBING INFORMATION

▼ COSENTYX 150 mg solution for injection in pre-filled pen. This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** COSENTYX 150 mg solution for injection in pre-filled pen. **Therapeutic Indications:** The treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; the treatment, alone or in combination with methotrexate (MTX), of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate. **Dosage & Method of Administration:** **Plaque Psoriasis:** Recommended dose in adults is 300 mg given as two subcutaneous injections of 150 mg. Dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. **Ankylosing Spondylitis:** The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. **Psoriatic Arthritis:** For patients with concomitant moderate to severe plaque psoriasis or who are anti TNF $\alpha$  inadequate responders, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For all other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. For all of the above indications, available data suggest that a clinical response is usually achieved within 16 weeks of treatment. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 16 weeks. The safety and efficacy in children below the age of 18 years have not yet been established. **Contraindications:** Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection (e.g. active tuberculosis). **Warnings/Precautions:** **Infections:** Cosentyx has the potential to increase the risk of infections. Serious infections have been observed in patients receiving Cosentyx in the post-marketing setting. Infections observed in clinical studies are mainly mild or moderate upper respiratory tract infections such as nasopharyngitis not requiring treatment discontinuation. Non serious mucocutaneous candida infections more frequently reported for secukinumab than placebo in psoriasis clinical studies. Caution in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, close monitoring and discontinue treatment until the infection resolves. Should not be given to patients with active tuberculosis. Anti tuberculosis therapy should be considered prior to initiation in patients with latent tuberculosis. **Inflammatory bowel disease:** Cases of new or exacerbations of Crohn's disease and ulcerative colitis have been reported. Caution should be exercised when prescribing to patients with inflammatory bowel disease including Crohn's disease and

ulcerative colitis. Patients should be closely monitored. **Hypersensitivity reactions:** In clinical studies, rare cases of anaphylactic reactions have been observed in patients receiving Cosentyx. If an anaphylactic or other serious allergic reactions occur, administration should be discontinued immediately and appropriate therapy initiated. **Latex-sensitive individuals:** The removable cap of the Cosentyx pre filled pen contains a derivative of natural rubber latex. **Vaccinations:** Live vaccines should not be given concurrently with Cosentyx. Patients may receive concurrent inactivated or non live vaccinations. **Concomitant immunosuppressive therapy:** Use in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. **Interactions:** Live vaccines should not be given concurrently with Cosentyx. In a study in subjects with plaque psoriasis, no interaction was observed between secukinumab and midazolam (CYP 3A4 substrate). No interaction seen when administered concomitantly with methotrexate (MTX) and/or corticosteroids. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. It is preferable to avoid the use of Cosentyx in pregnancy as there are no adequate data from the use of secukinumab in pregnant women. It is not known whether secukinumab is excreted in human milk. A decision on whether to discontinue breast feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Cosentyx must be made taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. The effect of secukinumab on human fertility has not been evaluated. **Undesirable Effects:** **Very common ( $\geq 1/10$ ):** Upper respiratory tract infections. **Common ( $\geq 1/100$  to  $< 1/10$ ):** Oral herpes, rhinorrhoea, diarrhoea, urticaria. **Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ):** Oral candidiasis, tinea pedis, otitis externa, neutropenia, conjunctivitis. **Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ):** Anaphylactic reactions. Please see Summary of Product Characteristics for further information on undesirable effects. **Legal Category:** POM. **Marketing Authorisation Holder:** Novartis Europharm Ltd, Vista Building, Elm Park, Merriem Road, Dublin 4, Ireland. **Marketing Authorisation Numbers:** EU/1/14/980/004-005. **Date of Revision of Abbreviated Prescribing Information:** October 2018. Full prescribing information is available upon request from: Novartis Ireland Limited, Vista Building, Elm Park Business Park, Elm Park, Dublin 4. Tel: 01-2204100 or at [www.medicines.ie](http://www.medicines.ie). Detailed information on this product is also available on the website of the European Medicines Agency <http://www.ema.europa.eu>

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie) E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Adverse events should also be reported to Novartis Ireland by calling 01-2080 612 or by email to: [drugsafety.dublin@novartis.com](mailto:drugsafety.dublin@novartis.com)

**References:** **1.** PJ Mease et al. Poster 2568. Presented at American College of Rheumatology Annual Meeting (ACR), 20-24 October 2018, Chicago, USA. **2.** Strand et al. Poster 2553. Presented at American College of Rheumatology Annual Meeting (ACR), 20-24 October 2018, Chicago, USA. **3.** H Marzo-Ortega et al. Poster 2556. Presented at American College of Rheumatology (ACR) Annual Meeting, October 19-24, 2018, Chicago, USA. **4.** A Deodhar et al. Poster 2583. Presented at American College of Rheumatology (ACR) Annual Meeting, October 19-24, 2018, Chicago, USA. **5.** McInnes et al. *Arthritis Research & Therapy* (2018) 20:113. **6.** Gossec et al. Poster SAT0463 presented at Annual European Congress of Rheumatology, 14-17 June 2017, Madrid, Spain. **7.** A Deodhar et al; *Clinical and Experimental Rheumatology* 2018. **8.** Baraliakos X et al. Abstract L13 presented at American College of Rheumatology (ACR) Annual Meeting, October 19-24, 2018, Chicago, USA. **9.** Bissonnette et al. Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to severe psoriasis through 5 years of treatment (SCULPTURE Extension Study); JEADV 2018.