Ongoing clinical studies funded by Versus Arthritis

The studies are grouped by condition, and are listed in alphabetical order. Click on further information to find out more from the Versus Arthritis website, or alternatively, where available, you can visit the study website for more information.

Childhood polyarteritis nodosa

An open label randomised controlled trial of mycophenolate mofetil versus cyclophosphamide for the induction of remission of childhood polyarteritis nodosa (MYPAN) 20094

Investigating the effectiveness and safety of the drug mycophenolate mofetil compared to the current standard cyclophosphamide for treatment of polyarteritis nodosa (PAN), a serious inflammatory blood vessel disease, in children. This study will compare the effectiveness and safety of the two treatments in children with PAN.

| Award holder: Dr Paul | Study website | Further information |
|-----------------------|---------------|---------------------|
| Brogan | | |
| | | |

| Fibromyalgia | | | | | |
|--|---------------|---------------------|--|--|--|
| Maintaining Musculoskeletal Health (MAmMOTH) Study 20748 | | | | | |
| The aim of this research project is to investigate the success of cognitive behaviour therapy by telephone in preventing the development of chronic widespread pain (CWP) in fibromyalgia patients and to assess its cost effectiveness | | | | | |
| Award holder: Professor Gary MacfarlaneStudy websiteFurther Information | | | | | |
| Fibromyalgia Optimal Management for patients with axial Spondyloarthritis (FOMAxS) 21378 | | | | | |
| The aim of this research is to determine the prevalence of fibromyalgia amongst patients with axial Spondyloarthritis, and if found to be sufficiently common, it will then determine the feasibility of a trial to determine how to effectively manage patients with both conditions. | | | | | |
| Award holder: Professor Gary Macfarlane | Study website | Further Information | | | |

General musculoskeletal pain

Production and evaluation of a clinical tool to screen older women with back pain for vertebral fractures (Vfrac) 21507

This study will consist of two stages. Firstly, the researchers will work with a group of older women who have had back pain in the last four months, asking them questions, and carrying out a physical



examination and X-rays. Statistics will be used to identify which questions and parts of the physical examination should go on the checklist. Secondly, they will follow up with this group of women to investigate what happened after the X-ray (for example they might have physiotherapy, or start on a new medication) to see if the checklist is likely to be helpful and save the NHS money in the longer term.

Award holder: Dr Emma ClarkStudy websiteFurther InformationIncreasing Physical Activity in Older People with Chronic Musculoskeletal Pain 21763

The aim of this research is to find out if a walking programme (iPOPP) will encourage people over the
age of 65, with joint pain, to be more active.Award holder: Dr Clare JinksStudy websiteFurther Information

Gout

Omega–3 fatty acids for the prophylaxis of acute attacks of gout on initiating urate lowering treatment – feasibility study for a randomized controlled trial 21506

This study aims to investigate further, based on evidence from previous studies, if omega-3 fatty acids, taken as a food supplement, are able to block the mechanisms by which urate crystals cause inflammation in the joints leading to gout attacks.

Award holder: Dr Abhishek Abhishek

Study website

Further Information

Inflammatory arthritis (multiple conditions, including rheumatoid arthritis)

Norfolk Arthritis Register (NOAR) 21229

This long-term study aims to understand the genetic basis of rheumatoid arthritis, the risk of cardiovascular disease in rheumatoid arthritis and the economic impact of inflammatory arthritis

 Award holder:
 Professor Alexander
 Study website
 Further Information

 MacGregor
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Lessening the Impact of Fatigue: Therapies for Inflammatory Rheumatic Diseases (LIFT) 21175

The aim of this research is to improve access to treatments which alleviate fatigue in people with inflammatory rheumatic conditions such as physical activity and talking therapy.

Award holder: Dr Neil Basu Study website Further Information

A randomised controlled trial of job retention vocational rehabilitation for employed people with inflammatory arthritis: the WORKWELL trial. 21761

The aim of the research is to investigate whether a work rehabilitation programme (WORKWELL) will improve the working lives of people with inflammatory arthritis. The programme is based upon a similar programme proven to be effective in the USA but adapted for the UK's social, health and economic systems. We previously funded a trial that showed WORKWELL could be delivered by therapists and had positive feedback from people with arthritis. This research project will provide a more rigorously controlled trial, testing both the effectiveness and cost-effectiveness of the programme.

Award holder: Professor Alison HammondStudy websiteFurther Information

Investigating the role of central nervous system pain in psoriatic arthritis 21964

Many people with psoriatic arthritis continue to experience persistent pain even after receiving effective treatments to reduce inflammation and other associated symptoms. The researchers believe that a type of pain originating in the central nervous system could play a role in contributing to pain in psoriatic arthritis, and this type of pain could respond to different treatments.

VERSUS ARTHRITIS

Juvenile Idiopathic Arthritis

A phase II trial of Tocilizumab in anti-TNF refractory patients with JIA associated uveitis (APTITUDE) 20659

The aim of this research is to see whether patients with JIA-associated uveitis get better when treated
with a drug called tocilizumab together with a standard treatment, methotrexateAward holder:Professor AthimalaipetStudy websiteFurther InformationRamananStudy websiteFurther Information

Biologics for Children with Rheumatic Diseases (BCRD) 20747

The development of new biologic drugs has significantly improved treatment for many children with
arthritis. However, there are concerns that biologics may increase the risk of infections or cancers
because they suppress the body's immune response. This study aims to investigate the current use,
effectiveness and risk of this group of drugs in children and young people with JIAAward holder:Professor Kimme HyrichStudy websiteFurther Information

Lupus and antiphospholipid syndrome

Safety and efficacy of BElimumab After B cell depleTion therapy in systemic LUPUS erythematosus (BEAT LUPUS) 20873

This research aims to investigate if belimumab can be used in combination with rituximab to treat lupus patients.

| Award holder: Professor | Study website | Further Information | | |
|---|-------------------------------------|-------------------------------------|--|--|
| Michael Ehrenstein | | | | |
| Rivaroxaban versus warfarin for stroke patients with antiphospholipid syndrome, with or without SLE (RISAPS): a randomised, controlled, phase II/III, non-inferiority trial 21517 | | | | |
| This research aims to determine w | hether a new blood thinning drug (a | anticoagulant), called rivaroxaban, | | |
| is as good or better than the standard treatment, warfarin, at treating patients with lupus/thrombotic | | | | |
| antiphospholipid syndrome, who have suffered blood clots in the arteries of the brain causing strokes. | | | | |
| Award holder: Dr Hannah | Study website | Further Information | | |
| Cohen | - | | | |

Osteoarthritis

The Effect of Denosumab on Pain and Bone Marrow Lesions in Symptomatic Knee Osteoarthritis: A Randomised Double Blind Placebo Controlled Clinical Trial (DISKO) 20829

At present, there are no treatments for knee osteoarthritis (OA) which both reduce pain and slow disease progression. Many patients with knee OA have abnormalities in their bone marrow, the flexible tissue inside bones, which are visible using advanced imaging and are thought to be a source of pain. This research study aims to determine whether denosumab, a drug used in the treatment of osteoporosis, can reduce the severity of knee pain and bone marrow changes in patients with OA.

| Award holder: Professor | Study website | Further Information | | |
|--|---------------|---------------------|--|--|
| Terence O'Neill | | | | |
| The clinical effectiveness and efficacy of splinting for thumb base osteoarthritis: a randomised controlled trial (OTTER II) 21019 | | | | |
| The aim of this study is to investigate the benefit of thumb splints for people with thumb base | | | | |
| osteoarthritis. | | | | |
| Award holder: Professor | Study website | Further Information | | |
| Joanna Adams | | | | |



| Topical and oral agent Usage a 21395 | tis Preoperative Package of care and Nutrition to Improve outcom | nes aT a Year (OPPORTUNITY) | | | |
|--|--|--|--|--|--|
| This is a feasibility study to refine the design of a major randomised controlled trial aimed at optimising non-operative measures for OA prior to surgery to improve patient outcomes following surgery. The non-operative therapy will consist of (1) weight loss, (2) an exercise programme, (3) analgesia and (4) footwear review. | | | | | |
| The intervention will be started imi | mediately after patients have been p of the incentive for behavioural char | | | | |
| Award holder: Professor Hamish Simpson | Study website | Further Information | | | |
| (specifically sulforaphane) on | | | | | |
| Previous research has indicated th | ing compound, gained from eating v nat exposure to these compounds a rthritis develops. This is the first clin al function in osteoarthritis. | t the levels found in the diet | | | |
| Award holder: Professor Alexander MacGregor | Study website | Further Information | | | |
| PROMOTE: A pragmatic, double-blind, randomised, placebo-controlled trial of methotrexate to treat painful knee osteoarthritis | | | | | |
| | | | | | |
| people with knee osteoarthritis (O, resonance imaging (MRI) will also | whether methotrexate is an effective A) compared to a placebo. A form o be used to examine whether metho these imaging studies will aid under | f imaging called magnetic ptrexate reduces inflammation | | | |
| people with knee osteoarthritis (O, resonance imaging (MRI) will also within the OA joint. The results of works. Award holder: Professor Philip | A) compared to a placebo. A form o be used to examine whether methor | f imaging called magnetic ptrexate reduces inflammation | | | |
| people with knee osteoarthritis (Or resonance imaging (MRI) will also within the OA joint. The results of works. Award holder: Professor Philip Conaghan A first-in-human study to test a | A) compared to a placebo. A form o be used to examine whether metho these imaging studies will aid under <u>Study website</u> scaffold treatment for early osted | f imaging called magnetic otrexate reduces inflammation standing of how methotrexate <u>Further information</u> oarthritis 21977 | | | |
| people with knee osteoarthritis (Or resonance imaging (MRI) will also within the OA joint. The results of works. Award holder: Professor Philip Conaghan A first-in-human study to test a In severe cases of osteoarthritis, a patients are unable to undergo. The severe case of osteoarthritis and the severe case of osteoarthritis. | A) compared to a placebo. A form o be used to examine whether methor these imaging studies will aid under <u>Study website</u> | f imaging called magnetic otrexate reduces inflammation standing of how methotrexate <u>Further information</u> oarthritis 21977 / treatment option, which some safety and suitability of treating | | | |

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| elusis |
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A randomised controlled study of oral prednisolone in early diffuse cutaneous systemic sclerosis (PredSS) 21021

The aim of this research is to investigate whether treatment with the steroid prednisolone is beneficial, in terms of safety and effectiveness, in patients with early diffuse cutaneous scleroderma.

| Award holder: Professor Ariane | Study website | Further Information |
|--------------------------------|---------------|---------------------|
| Herrick | | |

Sjogren's syndrome



| SALivary electro-stimulation for the treatment of dry mouth in patients with Sjogren's |
|--|
| syndrome: a multicentRe randomISEd sham-controlled double-blind study (SALRISE |
| 21233 |

Dry mouth is a common symptom of Sjögren's syndrome. It can compromise speech, swallowing, oral health and general quality of life. This study aims to establish whether electrostimulation of the salivary glands using a small electronic device can be used to treat dry mouth in people with Sjögren's syndrome.

| Award | holder: | Dr | Stefano | Study website | Further Information |
|--------|---------|----|---------|---------------|---------------------|
| Fedele | | | | | |

Spondyloarthritis

Do non-steroidal anti-inflammatory drugs (NSAIDs) reduce the appearance of sacroiliac joint bone marrow oedema on MRI, in spondyloarthritis? 21022

The aim of this clinical study is to investigate whether non-steroidal anti-inflammatory drugs (NSAIDs)
can prevent a true analysis of inflammation using magnetic resonance imaging (MRI).Award holder: Dr Gareth JonesStudy websiteFurther Information

Tendinopathy

Achilles Tendinopathy Management: A placebo randomised controlled trial evaluating platelet rich plasma injections (ATM) 20831

Many treatments exist for pain in the Achilles tendon of the heel, but there is no single best treatment. A new treatment has been developed which involves taking a sample of the patient's own blood and injecting part of the sample into the painful tendon. The aim of this research is to test whether this treatment is effective

| Award | holder: | Dr | Rebecca | Study website | Further Information |
|---------|---------|----|---------|---------------|---------------------|
| Kearney | | | | | |

Vasculitis

A randomised controlled trial comparing rituximab to standard immunosuppression as maintenance therapy in ANCA associated vasculitis (RITAZAREM) 19706

Aiming to show that rituximab (a biologic drug that inhibits B-cells) is better than standard treatments at stopping ANCA vasculitis returning over a four-year period. NCA vasculitis is a severe disease of unknown cause, in which the immune system attacks and injures various tissues in the body.

| Award holder: Dr | Study website | Further Information |
|---|--|----------------------------|
| David Jayne | | |
| Acquired immunodefic | ciency in ANCA associated vasculitis (AAV) 213 | 391 |
| Aptinoutrophil outoplasmic aptibody (ANCA) associated vasculitis, also known as AAV is successfully | | |

Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis, also known as AAV, is successfully
treated in some cases by a drug called rituximab. As this treatment leaves the immune system
compromised, it is recommended that patients also receive vaccinations to protect against flu and
pneumonia. The aim of this research is to see whether rituximab is negatively affecting these
vaccines, or whether a combination of vaccines would be better at reducing the risk of infection.Award holder:Dr Rona SmithStudy websiteFurther Information

Vitamin D

Does the beneficial effect of maternal gestational vitamin D supplementation on neonatal bone mass persist into childhood? Follow-up of the MAVIDOS placebo-controlled, double-blind, randomised trial (MAVIDOS-FU) 21231



Previous studies have shown that babies born to mothers with low levels of Vitamin D during pregnancy have low bone mass. The MAVIDOS trial investigated whether a mother taking Vitamin D during pregnancy impacts on the bone mass of her baby. It was found babies born during the winter, when Vitamin D levels naturally tend to be lowest, had improved bone mass. This research led by Professor Nicholas Harvey will follow on from the MAVIDOS trial and aims to test whether this improved bone mass continues into childhood (at 6 years old).

| Award holder: Professor | Study website | Further Information |
|-------------------------|---------------|---------------------|
| Nicholas Harvey | | |

