



# Ongoing clinical studies funded by Arthritis Research UK

The studies are listed in alphabetical order of the condition of the patients involved. Click on further information to find out more from the Arthritis Research UK website, or alternatively, where available, you can visit the study website for more information.

# ANCA associated 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 David Jayne

Study website

**Further Information** 

# Carpal tunnel syndrome

The clinical and cost effectiveness of steroid injection compared with night splints for carpal tunnel syndrome: a pragmatic randomised trial in primary care (INSTINCTS) 20105

Investigating whether steroid injections are more effective in the short term at reducing symptoms and improving hand function than using a night splint in patients with mild to moderate carpal tunnel syndrome (CTS). The cost effectiveness of steroid injections in comparison with night splints over six months will also be evaluated.

## 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 Brogan	Study website	<b>Further Information</b>
------------------------------	---------------	----------------------------

#### 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 Macfarlane	Study website	Further Information
Eibromyalaia Optimal Management for notionta with axial Spandylaerthritia		

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	Study website	Further Information
Macfarlane		

#### Fractures

Effect of bisphosphonate therapy on healing and clinical outcome of wrist fractures: randomised controlled trial (FaB) 19403

Looking at looking at the effect of bisphosphonate therapy (alendronate) on the healing and clinical outcomes of wrist fractures. Does alendronic acid slow or impair fracture healing? Does alendronic acid alters the clinical outcome after a wrist fracture?

Award holder: Professor Stuart	Study website	<b>Further Information</b>
Ralston		

General musculoskeletal pain			
Increasing physical activity in older people with chronic musculoskeletal pain: A brief and simple intervention to promote walking (iPOPP) 20608			
Investigating whether a brief and simple behavioural intervention increases the time spent walking in people over 65 with chronic pain that has an impact on their daily activities			
Award holder: Dr John McBeth Study website Further Information			
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 Clark	Study website	Further Information	

#### Gout

Nottingham gout treatment trial. Phase 2: two year randomised controlled trial of a nurse led package of care 19703

Finding out the effectiveness, in terms of treatment and cost of a nurse-led package of care in a community based study of gout patients is. This package reflects recommended best practice, and will be compared to ongoing standard care which is mainly led by GPs

Award holder: Professor Michael	Study website	Further Information
Doherty		

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	<b>Further Information</b>
------------------------------------	---------------	----------------------------

# 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

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	Award	holder:	Dr Neil	Basu
----------------------------	-------	---------	---------	------

Study website

Further Information

### **Juvenile Idiopathic Arthritis**

Randomised controlled trial of the clinical effectiveness, safety and cost effectiveness of adalimumab for the treatment of juvenile idiopathic arthritis associated uveitis (SYCAMORE) 19612

Aiming to find out how effective adding the drug adalimumab to methotrexate treatment is for treating children with severe uveitis (eye inflammation) and to establish whether this treatment is useful for preventing the serious complications that can arise from uncontrolled uveitis

Award holder: Professor Athimalaipet	Study website	<b>Further Information</b>
Ramanan		

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, methotrexate

Award holder: Professor Athimalaipet	Study website	<b>Further Information</b>
Ramanan		

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 JIA

Award holder: Professor Kimme Hyrich Study website

<u>Ebsite</u> <u>Further</u>

Further Information

#### **Knee replacement**

Targeted rehabilitation to improve outcome after knee replacement (TRIO) 20100

Investigating the effect of targeting specific physiotherapy at patients who are functioning poorly in the early post-operative period after knee replacement and determining whether this early treatment improves the pain, satisfaction and functional outcome at one year compared to a group receiving routine care. Also, investigating whether it is possible to identify characteristics that are predictors of poor outcome prior to surgery

Award holder: Professor Hamish	Study website	<b>Further Information</b>
Simpson		

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 Michael Ehrenstein	Study website	Further Information	
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 whether a new blood thinning drug (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 Cohen

Study website

Further Information

#### 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 Terence	Study website	Further Information
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 Joanna	Study website	<b>Further Information</b>
Adams		

Feasibility Study - Osteoarthritis Preoperative Package of care of Orthotics, Rehabilitation, Topical and oral agent Usage and Nutrition to Improve outcomes aT a Year (OPPORTUNITY) 21395

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 immediately after patients have been put onto the waiting list for joint replacement and take advantage of the incentive for behavioural change that this will create.

Award holder: Professor Hamish Simpson	Study website	Further Information

#### **Rheumatoid arthritis**

Identification of disease specific phenotypes associated with clinical and patient reported long-term outcomes in rheumatoid arthritis patients with moderate disease activity (MODRAS) 21023

The aim of this study is to investigate if the long-term outcomes differ between different groups of rheumatoid arthritis patients with moderate disease activity and whether there is a way of predicting patterns of disease progressions.

Award holder: Dr Suzanne Verstappen	Study website	<b>Further Information</b>
-------------------------------------	---------------	----------------------------

#### Sclerosis

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		

#### Shoulder pain

Is Arthroscopic sub-acromial decompression (ASAD) more effective than arthroscopy only (AO) for shoulder pain? (CSAW) 19707

Comparing an operation that removes bony spurs within the shoulder, which cause pain, to a simple investigative operation called arthroscopy to help clarify if spur removal is really necessary. Both these operations will be compared to no treatment to find out if shoulder arthroscopy is effective for patients with shoulder pain.

#### 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 Fedele

Study website

Further Information

# **Spondyloarthritis**

Web-based physiotherapy for people with axial spondyloarthritis: a cohort study (WEB-PASS) 20874

To investigate whether a web-based physiotherapy programme is an acceptable and effective way of helping people with axial spondyloarthritis manage their condition.

Award holder: Dr Lorna Paul	Study website	<b>Further Information</b>

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 Jones

Study website

Further Information

**Further 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

#### Vasculitis

Feasibility study - treatment of fatigue with physical activity and behavioural change support in vasculitis (FAB-V) 21199

The aim of this research is to assess the potential benefit of physical activity and behavioural support of that activity in treating people with vasculitis.

Award holder: Dr Lorraine Harper

Study website

Acquired immunodeficiency in ANCA associated vasculitis (AAV) 21391

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 Smith	Study website	<b>Further Information</b>
	-	

#### 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 Nicholas	Study website	<b>Further Information</b>
Harvey		