

Targeting synovitis in knee osteoarthritis

Submission date 21/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/05/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is the most common form of arthritis and remains one of the few chronic diseases of ageing for which there is little, if any, effective treatment. Symptomatic knee osteoarthritis affects roughly 12% of people aged 60 and over and, despite medical advances, remains a major source of pain and functional limitation. While the main feature of OA is loss of cartilage (the protective surface that allows your joints to move smoothly), all parts of the joint are affected. Treatment development has focused on protecting the cartilage from damage. Another important potential source of OA pain is the lining of the joint (the synovium). Inflammation of the synovium is seen in about 50% of the knees of patients with painful OA. Since corticosteroid drugs reduce inflammation, injection of corticosteroids into the knee might be effective for the treatment of OA pain. The aim of this study is to determine whether patients with evidence of synovial inflammation in OA respond better to corticosteroids than those who do not, and whether treatment response is associated with change in synovial inflammation.

Who can participate?

Patients aged 40 - 79 years with symptomatic knee osteoarthritis (OA).

What does the study involve?

Participants have their knee aspirated (where a sterile needle and syringe are used to drain fluid) and injected with the corticosteroid drug methylprednisolone acetate (Depo-Medrone). We measure the changes in knee pain and inflammation of the synovium following the injection.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

University of Manchester (UK)

When is the study starting and how long is it expected to run for?

May 2010 to May 2012

Who is funding the study?

Arthritis Research Campaign (ARC) (UK)

Who is the main contact?
Helen Williams
Helen.Williams@manchester.ac.uk

Study website

<http://www.inflammation-repair.manchester.ac.uk/roam>

Contact information

Type(s)

Scientific

Contact name

Mrs Helen Elizabeth Williams

Contact details

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Additional identifiers

EudraCT/CTIS number

2009-015849-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8358

Study information

Scientific Title

An open-label study of intra-articular steroid injection in the management of symptomatic knee osteoarthritis

Acronym

TASK v1.2

Study objectives

Osteoarthritis (OA) of the knee is a common disorder and at present there are few effective therapies. Intra-articular (IA) steroids have been used in the management of knee OA, however, the results of these studies have been variable. The aim of this study is to determine factors which predict the improvement in pain in patients treated with IA steroids. In total 120 patients with knee OA will be studied in an open label study of IA steroids.

The primary outcome measure will be the change in knee pain following steroid injection. We plan to determine whether features of synovitis at baseline assessed both clinically and on magnetic resonance imaging (MRI) imaging predict response to steroids and whether change in features of synovitis, assessed using serial MRI scanning are associated with change in pain status. We will also determine the predictive ability of synovial fluid parameters and other factors including quality of life predict the response to steroids.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicester 2 REC, 27/01/2010, ref: 09/H0402/107

Study design

Single-centre non-randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Can be found at <http://www.inflammation-repair.manchester.ac.uk/roam>

Health condition(s) or problem(s) studied

Topic: Musculoskeletal, Primary Care Research Network for England; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions

Participants will have their index knee aspirated and injected with 80 mg methylprednisolone acetate (Depo-Medrone). Subjects will have one injection only during the course of the study.

Follow up length: 6 months

Study entry: registration only

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Depomedrone

Primary outcome measure

Change in knee pain, analysis will focus on whether change in pain level from baseline to one week after the injection is given

Secondary outcome measures

1. Visual Analogue Scale (VAS) - global knee pain
2. VAS - pain on nominated activity
3. VAS - wellness
4. Knee injury and Osteoarthritis Outcome Score (KOOS) subscales

Data collected at each study visit, baseline, week 1 and 1 x follow-up.

Overall study start date

04/05/2010

Completion date

15/12/2014

Eligibility**Key inclusion criteria**

1. Age 40 - 79 years
2. Male or female
3. Ambulatory (not wheelchair bound)
4. Able and willing to attend or comply with intervention and follow up
5. Within the last 24 months:
 - 5.1. Radiological (X-ray) evidence of grade 2 or more OA
 - 5.2. Evidence of significant OA on MRI scan
 - 5.3. Documented evidence of at least grade 2 arthritis on arthroscopy
6. Moderate knee pain lasting 48 hours in the past 2 weeks
7. Presence of clinically apparent knee effusion
8. Written informed consent
9. Glomerular filtration rate (GFR) greater than 44 ml/min

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 120; UK sample size: 120

Key exclusion criteria

1. Secondary OA - septic arthritis, gout
2. History of inflammatory arthritis
3. Previous intra-articular Ostenil or steroid injection within 6 months
4. Previous knee surgery (including cartilage surgery) or arthroscopy within 6 months
5. Inability to understand the procedures
6. Pregnancy
7. Chronic kidney disease with estimated glomerular filtration rate (eGFR) greater than or equal to 44 ml/min
8. Concurrent life threatening illness
9. Implants which prohibit safe use of MRI scan including cochlear implants/metal objects in the body including joint prosthesis, cardiac or neural pacemakers, hydrocephalus shunts, intrauterine device or coil
10. Known hypersensitivity to Depomedrone or any components of its excipients
11. Systemic infection (unless specific anti infective therapy is employed)

Date of first enrolment

04/05/2010

Date of final enrolment

10/06/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Manchester

Manchester

United Kingdom

M13 9PT

Study participating centre

Salford Royal NHS Foundation Trust

Stott Lane

Salford

United Kingdom

M6 8HD

Sponsor information

Organisation

Salford Royal NHS Foundation Trust (UK)

Sponsor details

Hope Hospital
Stott Lane
Salford
England
United Kingdom
M6 8HD

-
lloyd.gregory@manchester.ac.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.srht.nhs.uk>

ROR

<https://ror.org/019j78370>

Funder(s)**Funder type**

Charity

Funder Name

Arthritis Research Campaign (ARC) (UK)

Results and Publications**Publication and dissemination plan**

All publications will be open access and on PubMed when available

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No
Results article	results	08/05/2017		Yes	No
HRA research summary			28/06/2023	No	No