ISRCTN07329370 https://doi.org/10.1186/ISRCTN07329370

Targeting synovitis in knee osteoarthritis

Submission date
21/05/2010

Recruitment status
No longer recruiting

Registration date
21/05/2010

Overall study status
Completed

Last Edited
10/05/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
University of Manchester
ARC Epidemiology Unit
Stopford Building
Oxford Road
Manchester
United Kingdom
M13 9PT
-
Helen.Williams@manchester.ac.uk

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