

# Improving outcomes for patients with hip osteoarthritis: The Hip Injection Trial (HIT)

<b>Submission date</b> 24/07/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/12/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hip osteoarthritis (OA) is a very common condition that causes pain and can affect ability to do day to day activities. There have been several studies on treatments for OA including joint injections. However, little is known about the best treatments for patients with moderate to severe hip OA. This trial aims to find out whether best current treatment in addition to a single steroid and local anaesthetic injection is effective at reducing pain in patients with hip OA when compared to best current treatment and a single local anaesthetic injection, or best current treatment alone.

### Who can participate?

Participants recruited either from primary care referrals to orthopaedics, rheumatology and two musculoskeletal services in Staffordshire or those identified by a search of local GP records and invited by letter sent from their GPs. Patients aged 40 years and over and who have experienced pain from hip OA for at least 6 weeks.

### What does the study involve?

Participants are randomly allocated into one of three groups. Those in group 1 are given the best current treatment plus a single steroid and local anaesthetic injection. The steroid is a drug called Triamcinolone Acetonide. This drug is widely used to treat joint pain and arthritis. Participants in group 2 are given the best current treatment and a local anaesthetic injection. Participants in group 3 are given only the best current treatment. All participants are then asked to complete up to 5 questionnaires over the next 6 months. Interviews are also conducted with trial participants who consent to take part in the qualitative study about their experience of the trial and living with hip pain.

### What are the possible benefits and risks of participating?

It is considered that there are minimal risks to participants associated with the trial interventions as both the injections are being given in accordance with routine care. The duration of the clinic is longer than for usual care and patients attending clinic are asked not to drive themselves because they will be unable to drive themselves afterwards if they receive an injection. Participants will be asked to complete up to 5 questionnaires and there is some burden with regards to the time taken to complete them. However, the questionnaires have been designed

to be as simple and clear to read as possible. A small sample of participants will take part in qualitative interviews. It is possible that participants may become upset when talking about their lives but the interviewer will be sensitive to this. In terms of potential benefit to research participants. The treatments in this trial are already used in the management of osteoarthritis, but we cannot guarantee that one is better than the another and it is possible that neither treatment works for some patients. This trial will allow us to compare the benefits of each treatment in a large group of patients. The results from this trial may help us to decide how best to treat people with hip osteoarthritis in the future.

Where is the study run from?

Keele Clinical Trials Unit, Arthritis Research UK Primary Care Centre, Keele University (UK)

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

August 2014 to May 2019.

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Edward Roddy

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

2014-003412-37

### IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

323/12

## **Study information**

### **Scientific Title**

For patients with painful hip OA; comparing 1) best current treatment plus an ultrasound-guided intra-articular hip injection of corticosteroid (triamcinolone acetonide 40mg) with 1% lidocaine hydrochloride with either 2) best current treatment alone or 3) best current treatment plus an ultrasound-guided intra-articular hip injection of 1% lidocaine hydrochloride. a randomised, clinical, single-blind, three-arm, parallel group pragmatic trial in patients with hip OA with a linked qualitative study

### **Acronym**

HIT - the Hip Injection Trial

### **Study objectives**

This trial aims to find out whether best current treatment in addition to a single steroid and local anaesthetic injection is effective at reducing pain in patients with hip OA when compared to best current treatment and a single local anaesthetic injection, or best current treatment alone.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee North West - Greater Manchester South, 15/07/2015, ref: 15/NW/0546

### **Study design**

A randomized, clinical, single-blind, three-arm, parallel-group pragmatic trial in patients with hip OA with a linked qualitative study.

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

## Osteoarthritis of the hip

### Interventions

1. Best current treatment only
2. Best current treatment plus an ultrasound-guided intra-articular hip injection of corticosteroid (triamcinolone acetonide 40 mg) with 1% lidocaine hydrochloride
3. Best current treatment plus an ultrasound-guided intra-articular hip injection of 1% lidocaine hydrochloride alone

### Intervention Type

Mixed

### Primary outcome measure

Pain, measured using the Numerical Rating Scale score for current pain (Dworkin 2005) at baseline, 2 weeks, 2 months, 4 months and 6 months

### Secondary outcome measures

1. Joint function, measured using Western Ontario and McMaster University Arthritis Index (WOMAC v3.1) at baseline, 2 months, 4 months and 6 months
2. Participant's self-reported global impression of change, measured at 2 weeks, 2 months, 4 months and 6 months
3. General health, measured using SF-12 at baseline, 2 months, 4 months and 6 months
4. Sleep disturbance, measured using a Likert-type scale at baseline, 2 months, 4 months and 6 months
5. Pain self-efficacy, measured at baseline, 2 months, 4 months and 6 months
6. Modified Brief Illness Perceptions Questionnaire, measured at baseline, 2 months, and 6 months
7. Satisfaction and experience, measured at baseline, 2 months and 6 months
8. Health status, measured using EQ5D-5L at baseline, 2 weeks, 2 months, 4 months and 6 months
9. Employment status, measured at baseline and 6 months
10. Performance at work, measured at baseline, 2 months, 4 months and 6 months
11. Absenteeism from work, measured at baseline, 2 months and 6 months
12. Health care utilisation, measured at 2 months and 6 months
13. Participant-incurred costs, measured at 2 months and 6 months
14. Other hip injections received, measured 2 months and 6 months
15. Self-reported adverse events, measured at 2 weeks, 2 months and 6 months
16. Adherence to best current treatment advice, measured at 2 months, 4 months and 6 months

### Overall study start date

01/08/2014

### Completion date

31/05/2019

## Eligibility

### Key inclusion criteria

1. Male or female aged  $\geq 40$  years
2. A clinical diagnosis of unilateral or bilateral hip OA, and confirmed on plain radiography within the last 24 months, as made by a trained clinician in the musculoskeletal service

3. Moderate to severe current hip pain
4. Symptom duration of episode of at least 6 weeks
5. Hip pain occurring on most days of the last month
6. Informed written consent provided by the patient

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

40 Years

**Sex**

Both

**Target number of participants**

204

**Total final enrolment**

199

**Key exclusion criteria**

1. Hip pain due to other disorders (e.g. trochanteric bursitis, avascular necrosis, pain referred from back)
2. Intra-articular corticosteroid injection into the affected hip or ipsilateral trochanteric bursa injection within the preceding 3 months
3. Any previous surgery on the affected hip
4. Clinical suspicion of local or systemic sepsis or infection
5. Current or previous infection of the affected hip
6. Significant trauma to the affected hip requiring immobilisation in the previous 3 months
7. Unwillingness to undergo study interventions
8. Unable to understand and complete self-report questionnaires written (or spoken) in English
9. Significant illness (known or suspected) including, but not limited to:
  - 9.1. Inflammatory joint disease (e.g. rheumatoid arthritis, seronegative spondyloarthropathy (ankylosing spondylitis, psoriatic arthritis, reactive arthritis, inflammatory-bowel disease associated inflammatory arthritis))
  - 9.2. Polymyalgia rheumatica or other condition requiring regular oral steroid use
  - 9.3. Malignancy (where malignancy is thought to be causing hip pain e.g. suspected bony metastases)
  - 9.4. Any other severe medical illness which in the opinion of the local Principal Investigator (or other authorised clinical delegate) precludes trial participation
10. Pregnant or lactating females
11. Receiving anticoagulants (warfarin, dabigatran, rivaroxaban, apixaban or low molecular weight heparin)
12. Any history of hypersensitivity to triamcinolone acetonide or 1% lidocaine hydrochloride or any of their excipients (1N Hydrochloric Acid QS, 1N Sodium Hydroxide QS, Benzyl alcohol, Polysorbate 80, Sodium carboxymethylcellulose and Sodium chloride)
13. Contraindications to use of local anaesthetic: Complete heart block and hypovolaemia

**Date of first enrolment**

01/10/2015

**Date of final enrolment**

31/05/2018

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Keele Clinical Trials Unit (CTU)**

Arthritis Research UK Primary Care Centre

Keele University

Newcastle-under-Lyme, Staffordshire

United Kingdom

ST5 5BG

## **Sponsor information**

**Organisation**

Keele University

**Sponsor details**

Keele University Science & Business Park

IC1 Building

Staffordshire

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**Sponsor type**

University/education

**ROR**

<https://ror.org/00340yn33>

## **Funder(s)**

**Funder type**

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Research results will be published in scientific journals and the relevant manuscripts made available in the public domain as required by the funder (NIHR RfPB). We will also provide information for appropriate public forums. Once the results of the trial have been published participants will be sent a summary of the findings.

## Intention to publish date

30/06/2020

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	18/07/2018		Yes	No
<a href="#">Basic results</a>			09/06/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		06/04/2022	18/08/2023	Yes	No
<a href="#">Results article</a>	qualitative interview data	31/10/2023	01/11/2023	Yes	No
<a href="#">Results article</a>	Cost-effectiveness	12/12/2023	13/12/2023	Yes	No