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

Submission date
24/07/2015

Recruitment status
No longer recruiting

Registration date
28/07/2015

Overall study status
Completed

Last Edited
13/12/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 GPPatients 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 n 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 completed 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-003412-37

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Male or female aged ≥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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex

All

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
United Kingdom

England

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

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

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?
Results article		06/04/2022	18/08/2023	Yes	No
Results article	qualitative interview data	31/10/2023	01/11/2023	Yes	No
Results article	Cost-effectiveness	12/12/2023	13/12/2023	Yes	No
Protocol article	protocol	18/07/2018		Yes	No
Basic results			09/06/2020	No	No
HRA research summary			28/06/2023	No	No