

Efficacy of intra-articular injection for end stage hip osteoarthritis: can pain and disability be relieved?

Submission date 08/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NT/41/04/JC

Study information

Scientific Title

Study objectives

Intra-articular injection of either steroids or Hyaluronic Acid (HA) are now being recommended for patients with knee OsteoArthritis (OA), but there is a lack of studies in hip OA to demonstrate its safety and efficacy. Due to lack of adequate guidance, the lack of response in early research may reflect poor accuracy of injection, rather than lack of benefit.

This study, using an injection technique proven to be accurate, will aim to demonstrate the duration of objective improvement in pain, disability (function and patients global health assessment) and objective mobility in patients with end stage hip osteoarthritis with ultrasound guided hip injection compared to standard care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval was initially obtained [2002] from the Northumberland Ethics committee with revisions to the protocol being approved in Aug 2005, reference number: NLREC 54/2002.

Subsequently, approval was also obtained from Newcastle/North Tyneside Committee in Aug 2005, reference number: NNT SSA 05/Q0905/155.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hip osteoarthritis

Interventions

The study is a prospective, randomised, blind, controlled (three arm) trial, with a further randomised standard care arm. The four groups are:

1. Standard care (no injection)
2. Standard care and injection of 3 ml normal saline
3. Standard care and injection of 3 ml steroid (depomedrone 120 mg)
4. Standard care and injection of 3 ml durolane (injection will be performed under local anaesthetic with ultrasound guidance)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

1. Depomedrone
2. Durolane

Primary outcome measure

1. Visual Analogue Scale (VAS) for global pain
2. Pain and function scales of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
3. Numact (objective activity monitor)

Secondary outcome measures

1. Euroqol EQ-5D
2. Outcome Measures in Rheumatoid Arthritis Clinical Trials-Osteoarthritis Research Society International (OMERACT-OARSI)

Overall study start date

01/08/2005

Completion date

01/05/2007

Eligibility

Key inclusion criteria

1. Age ≥ 50 years
2. Primary hip osteoarthritis
3. Listed for Total Hip Replacement (THR)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Secondary hip OA
2. Collapse of femoral head on anteroposterior pelvic radiograph
3. Listed for bilateral THR
4. Co-morbid conditions resulting in gross lower limb asymmetry (e.g. stroke, amputees, severe leg shortening)
5. Inability to communicate in verbal or written English

Date of first enrolment

01/08/2005

Date of final enrolment

01/05/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Institute of Cellular Medicine

Newcastle

United Kingdom

NE2 4HH

Sponsor information**Organisation**

Northumbria Healthcare NHS Trust (UK)

Sponsor details

North Tyneside General Hospital

Rake lane

North Shields

England

United Kingdom

NE29 8NH

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01gfeyd95>

Funder(s)

Funder type

Government

Funder Name

Northumbria Healthcare NHS Trust

Funder Name

NT/41/04/JC - an 'own account' trial, funded via the NHS R&D Support Funding stream

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011		Yes	No