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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

Registration date
10/02/2006

Overall study status
Completed

Last Edited
01/10/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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)

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Institute of Cellular Medicine
Newcastle
United Kingdom
NE2 4HH

Sponsor information

Organisation
Northumbria Healthcare NHS Trust (UK)

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

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