Comparative study between intraarticular ostenil versus orthovisc

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
13/02/2017	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr VS Dachepalli

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0237142757

Study information

Scientific Title

Comparative study between intraarticular ostenil versus orthovisc

Study objectives

Which one is most effective in providing short to medium term relief for patients with osteoarthritis of the knee, either ostenil or orthovisc, if used as a single course?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective masked observer 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

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

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Osteoarthritis of the knee

Interventions

Intraarticular ostenil versus orthovisc

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ostenil, orthovisc

Primary outcome measure

- 1. WOMAC Western Ontario and McMaster Universities Arthritis Index
- 2. VAS pain scale

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2004

Completion date

31/12/2006

Eligibility

Key inclusion criteria

- 1. Male and female
- 2. Diagnosed with osteoarthritis of the knee

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

146

Key exclusion criteria

- 1. Other known inflammatory arthropathies eg psoriasis, sero-negative arthropathies
- 2. Grade 4 osteoarthritis on the Kellgren score
- 3. Previous intra articular injections (except previous steroids or local anaesthetic)
- 4. Laxity or deformity
- 5. Uncontrolled diabetes, pregnancy, major existing medical problems, liver and renal diseases
- 6. Immunosuppressed and those on high dose steroids for any reason
- 7. Local infection at site and patients with gross pedal oedema
- 8. Patients with hypersensitivity to hyaluronic acid
- 9. Patients unwilling to participate or unable to give consent

Date of first enrolment

01/05/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
St Helens & Knowsley Hospitals NHS Trust
Prescot
United Kingdom
L35 5DR

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

St Helens and Knowsley Hospitals NHS Trust (UK) NHS R&D Support Funding

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 summaryNot provided at time of registration