ISRCTN43185756 https://doi.org/10.1186/ISRCTN43185756

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
St Helens & Knowsley Hospitals NHS Trust
Orthopaedics
Whiston Hospital
Prescot
United Kingdom
L35 5DR

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 summary
Not provided at time of registration