

Comparative study between intraarticular ostenil versus orthovisc

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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**

United Kingdom

England

Study participating centre

St Helens & Knowsley Hospitals NHS Trust

Prescot

United Kingdom

L35 5DR

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration