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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
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes