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Effect of sodium hyaluranate on recovery after arthroscopic knee surgery

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/10/2011	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0155126378

Study information

Scientific Title

Study objectives
To determine effect of single post-operative intra-articular injection of sodium hyaluranate on the pain and joint function following arthroscopic knee surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added July 2008: approved by Oldham Local Ethics Research Committee

Study design
Prospective randomised controlled single blinded single centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Knee

Interventions
Single post-operative intra-articular injection of sodium hyaluranate vs placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
sodium hyaluranate

Primary outcome measure

Added July 2008:
Pain on weight bearing as measured on 10 point Visual Analogue score.

Secondary outcome measures
Added July 2008:
1. Pain on rest and squatting, as measured on 10 point Visual Analogue score
2. SF-12 and WOMAC score

Overall study start date
10/04/2003

Completion date
31/08/2003

Eligibility

Key inclusion criteria
Male and female patients 18-60 waiting for their arthroscopic knee surgery will be invited to participate.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
25 patients approx

Key exclusion criteria
1. Infection
2. Inflammatory arthropathy
3. Patellofemoral disease
4. Allergy to Viscoseal

Date of first enrolment
10/04/2003

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthopaedics Department
Oldham
United Kingdom
OL1 2JH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Pennine Acute Hospitals NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Poster results	poster results	02/12/2004		No	No