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The effectiveness and cost-effectiveness of arthroscopic lavage in the treatment of osteoarthritis of the knee

Submission date
08/06/2006

Recruitment status
No longer recruiting

Registration date
09/06/2006

Overall study status
Completed

Last Edited
11/07/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.charttrials.abdn.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 03/48/01

Study information

Scientific Title

Acronym
KORAL

Study objectives
This is a pilot study, the design of which has been informed by extensive qualitative feasibility work, to assess in two UK centres (Aberdeen and North Staffordshire) the feasibility of mounting a multicentre, placebo-controlled trial to evaluate the effectiveness of arthoscopic lavage for osteoarthritis of the knee.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 30/06/2010 to 31/10/2008.

Protocol V2 dated July 2006 is available on http://www.hta.ac.uk/protocols/200300480001.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application submitted to MREC, Scotland as of 09/06/06

Study design
Pilot, 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

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
1. Arthroscopic lavage (+/- debridement as deemed clinically necessary)
2. Placebo arthroscopic lavage
3. Non-operative management with specialist re-assessment

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. To examine whether the trial processes as currently planned are appropriate, feasible and acceptable to patients, clinicians and the trial office staff
2. To quantify the throughput of eligible patients
3. To quantify the number of patients approached and the proportion of patients who would accept randomisation to the trial
4. To examine the acceptability of the trial information material to patients

Secondary outcome measures
The secondary research outcomes of the main trial (in which we anticipate the pilot patients' data being included) are:
1. General quality of life as measured by 12-item short form questionnaire (SF-12)
2. Patient utility as measured by EQ5D
3. Non-steroidal anti-inflammatory drug (NSAID) or analgesic use
4. Use of other treatments outside the trial interventions
5. Use and cost of health services
6. Cost-effectiveness - incremental cost per quality adjusted life year gained

Overall study start date
01/07/2005

Completion date
31/10/2008

Eligibility

Key inclusion criteria
1. Adults (18 years or older) with radiological evidence of osteoarthritis (OA) of the knee who might routinely be considered for arthroscopic lavage
2. Fit for general anaesthetic (American Society of Anesthesiologists [ASA] grade 1 and 2)
3. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Approximately 70

Key exclusion criteria
1. Patients for whom the orthopaedic surgeon judges that arthroscopic lavage is clearly indicated
2. Patients for whom arthroplasty is clearly indicated
3. Clear contraindication to general anaesthesia
4. Inability to fill in follow-up questionnaires

Date of first enrolment
01/07/2005

Date of final enrolment
31/10/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Health Services Research Unit
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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?
Results article	results	21/02/2011		Yes	No