

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

☐ Prospectively registered

☐ Protocol

Registration date
09/06/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
11/07/2011

Condition category
Musculoskeletal Diseases

☐ 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

Contact name

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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 arthroscopic 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

Quarry Hill

Leeds

United Kingdom

LS2 7UE

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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