

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

<b>Submission date</b> 08/06/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/07/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

Scotland

### **Study participating centre**

**Health Services Research Unit**

Aberdeen

United Kingdom

AB25 2ZD

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **ROR**

<https://ror.org/03sbpja79>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## **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?
<a href="#">Results article</a>	results	21/02/2011		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes