# The cost-effectiveness of Magnetic Resonance Imaging (MRI) for investigation of the knee joint

Submission date Recruitment status [ ] Prospectively registered 25/04/2003 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 25/04/2003 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 02/09/2009 Musculoskeletal Diseases

### 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 HTA 93/26/16

# Study information

### Scientific Title

### Study objectives

This study considered the role of Magnetic Resonance Imaging (MRI) in the diagnosis of knee injuries in a District General Hospital (DGH) setting. The principal objective was to identify whether the use of MRI had a major impact on the clinical management of patients presenting with chronic knee problems, in whom surgery was being considered, whether it reduced overall costs and whether it improved patient outcome.

### In addition, the research:

- 1. Explored the 'diagnostic accuracy' of initial clinical investigation of the knee by an orthopaedic trainee, consultant knee specialist and consultant radiologist
- 2. Considered the variability and diagnostic accuracy of interpretations of knee MRI investigations between radiologists
- 3. Measured the strength of preference for the potential diagnostic/therapeutic impact of knee MRI (i.e. the avoidance of surgery)

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Single centre, randomised controlled trial

## Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

# Study type(s)

Screening

### Participant information sheet

# Health condition(s) or problem(s) studied

Musculoskeletal injury

### **Interventions**

The research was based on a single-centre randomised controlled trial conducted at Kent and Canterbury Hospital.

Patients were randomised to:

- 1. Investigation using an MRI scan (MRI trial arm), or
- 2. Investigation using arthroscopy (no-MRI trial arm)

### Investigation of diagnostic accuracy:

For the investigation of diagnostic accuracy of initial clinical investigation, the sample comprised 114 patients recruited in a separate study conducted at St Thomas Hospital. The sample was drawn from patients presenting at the Accident and emergency Department with an acute knee injury. All study patients received an MRI scan, but initial diagnosis was made without access to the scan or the radiologists report. After 12 months, all clinical notes and MRI scans of study patients were reviewed and a final reference standard diagnosis for each patient was reached. Comparison was made between the diagnosis recorded by each clinician (i.e. orthopaedic trainee, knee specialist and consultant radiologist) and the reference diagnosis.

### Investigation of the generalisability of results:

For this substudy, the MRI images from 80 patients (recruited at St Thomas Hospital) were interpreted independently by seven consultant radiologists at DGHs and the St Thomas Hospital MRI radiologist. For each area of the knee, the level of agreement (measured using weighted kappa) between the responses of the eight radiologists and the reference standard diagnosis was assessed.

#### Investigation of preferences:

The investigation of potential patient preferences for the diagnostic/therapeutic impact of MRI was explored using a discrete choice conjoint measurement research design. Choices involved selecting between two alternative scenarios described using four attributes, and data were collected from 585 undergraduate sports science students and analysed using a random-effects probit model.

### Intervention Type

Other

### Phase

**Not Specified** 

#### Primary outcome measure

The study investigated the benefits of knee MRI at two levels:

- 1. Diagnostic/therapeutic impact (i.e. avoidance of surgery)
- 2. Patient outcome (using the 36-item Short Form questionnaire [SF-36] and the EuroQoL quality-of-life measurement instruments [EQ-5D]); quality of life was assessed at baseline and at 6 and 12 months

Costs were assessed from the perspectives of the NHS and patients. All analyses were by intention to treat.

#### Secondary outcome measures

No secondary outcome measures

# Overall study start date

01/01/1996

### Completion date

# **Eligibility**

### Key inclusion criteria

Patients attending with knee problems in whom surgery was being considered were recruited from routine orthopaedic clinics.

### Participant type(s)

**Patient** 

### Age group

**Not Specified** 

### Sex

Both

### Target number of participants

118

### Key exclusion criteria

No exclusion criteria

### Date of first enrolment

01/01/1996

### Date of final enrolment

31/12/1998

# Locations

### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Health Services Management Centre Birmingham

United Kingdom B15 2RT

# **Sponsor information**

Organisation

### Department of Health (UK)

# Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

### 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?
Other publications	HTA monograph	01/12/2001		Yes	No
	results				

Results article 01/03/2004 Yes No