ISRCTN17898966 https://doi.org/10.1186/ISRCTN17898966

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
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
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

31/12/1998

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
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Sponsor information

Organisation

Department of Health (UK)

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

Results article	01/03/2004	Yes	No