

Randomised controlled trial of open access to Magnetic Resonance Imaging (MRI) versus direct referral to orthopaedic surgeons for General Practitioner (GP) patients with continuing knee problems

Submission date 02/05/2001	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/05/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.york.ac.uk/healthsciences/centres/trials/damask/dam2.htm>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0001133 (P/Care init)

Study information

Scientific Title

Acronym

DAMASK (Direct Access to Magnetic resonance imaging: Assessment for Suspect Knees)

Study objectives

Each year 15% of all patients consult General Practitioners (GPs) for musculo-skeletal disorders. Examination of the knee is now one of the commonest musculo-skeletal applications of Magnetic Resonance Imaging (MRI). There is evidence that MRI allows accurate assessment of meniscal and ligamentous injuries of the knee. With explicit clinical indications in selected patients it can avoid an expensive invasive arthroscopy, reducing the waiting times for those who do need one. However, whether management using MRI affects patients quality of life has not been rigorously evaluated. Hence there is uncertainty about whether recommending open access MRI to avoid hospital referral is appropriate. This reflects wide variation both in GPs access to, and use of MRI, and in associated costs. Thus the question whether patients presenting to GPs with continuing knee problems should be referred for an MRI scan or directly to an orthopaedic surgeon is crucial to patient management and outcome, and thus to cost-effectiveness.

Hypothesis:

1. To evaluate:

a. whether the early use of MRI through open access affects subsequent diagnosis and management

b. whether it improves patient outcomes

c. whether it reduces net costs to the NHS, patients and society

2. To explore patient and practitioner preferences for open access to MRI and to investigate the generalisability of results obtained from the three experimental sites in York, Wrexham and Aberdeen

By including Cardiff, where direct access to MRI has been available for eight years, we shall study the effect of such access on the case mix of GP referrals for direct MRI and referrals to the orthopaedics department.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial protocol was designed to comply with the Declaration of Helsinki as adopted by the World Medical Association. UK Northern and Yorkshire Multi-Centre Research Ethics Committee approved the protocol (reference number MREC/1/3/59).

Study design

Multicentre, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet**Health condition(s) or problem(s) studied**

Knee problems

Interventions

All general practice staff are invited to a training session about the appropriate use of MRI and interpretation of findings.

Within practices individual participants will be randomised between:

1. The local radiology department for an MRI scan - depending on the result of the scan the GP might then refer the participant to be seen by an orthopaedic surgeon; and
2. The local orthopaedic department for a consultation with the specialist - depending on the result of this visit, the surgeon might then send the participant for an MRI scan.

To ensure that the evaluation covers events up to and including arthroscopy we shall follow patients from random allocation for 24 months using questionnaires asking about their general health and experience of knee pain. Economic analyses will compare benefits to participants with costs to both the NHS and participants themselves.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The primary outcome measure is the change in the physical functioning sub-scale of the Short Form 36-item questionnaire (SF-36) at six months. A change of 6.75 points on the scale has been agreed as being clinically significant.

Secondary outcome measures

No secondary outcome measures

Overall study start date

03/01/2002

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. People aged between 18 and 55
2. Suspected internal derangement of the knee suggesting meniscal or ligamentous patello-femoral joint-pain
3. Continuing symptoms at least six weeks after the initial consultation during the study period despite conservative treatment (e.g., analgesics, physiotherapy or tubigrip)
4. GP is considering orthopaedic or MRI referral

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

500

Key exclusion criteria

1. The GP judges that urgent orthopaedic referral is necessary at the initial consultation
2. Suspected osteoarthritis or other non-traumatic arthropathy
3. Isolated patello-femoral joint pain
4. Previous MRI scan within this episode of care
5. Previous surgical intervention (excluding diagnostic arthroscopy) on the same knee
6. Contraindications to the use of MRI, for example pacemaker, intra-cranial aneurysm clips, or orbital metallic foreign body
7. Patients who reside in Orkney or Shetland

Date of first enrolment

03/01/2002

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Health Sciences and Clinical Evaluation

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

Sponsor details

Heslington

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Sponsor type

University/education

Website

<http://www.york.ac.uk/>

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0001133)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Protocol article	protocol	13/10/2006		Yes	No
Results article	results re influence of MRI on GP's decision	01/08/2007		Yes	No
Results article	results re cost-effectiveness of MRI	01/11/2008		Yes	No
Results article	results re effectiveness of GP's access to MRI	01/11/2008		Yes	No
Results article	participant feedback survey results	01/12/2010		Yes	No