ISRCTN76616358 https://doi.org/10.1186/ISRCTN76616358

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

Registration date
02/05/2001

Overall study status
Completed

Last Edited
01/02/2011

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
Dr Ian Russell

Contact details
Department of Health Sciences and Clinical Evaluation
University of York
Alcuin College
Heslington
York
United Kingdom
YO10 5DD

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
York
England
United Kingdom
YO10 5DD

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