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The impact of magnetic resonance imaging on the rate of arthroscopy and patient outcome for knee disorders requiring arthroscopy

Submission date 16/11/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/01/2007	**Overall study status** Completed	
Last Edited 25/04/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Katie Roebuck

Contact details
Medical Research Unit
Thornburrow Drive
Stoke on Trent
United Kingdom
ST4 7QB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
MRIA

Study objectives
To determine the usefulness, effectiveness and efficieny of Magnetic Resonance Imaging (MRI) compared with diagnostic arthroscopy in the management of mechanical knee problems at six weeks and six months to follow up. The specific objectives are:
1. To measure the likely reduction in arthroscopies of using MRI and selected diagnostic arthroscopies compared with diagnostic arthroscopy alone.
2. Determine patient-based clinical economic outcomes of care when using MRI and selected diagnostic arthroscopy compared with arthroscopy alone in the management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Staffordshire Local Research Ethics Committee on 04/06/2001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mechanical Disorder of the knee requiring Arthroscopy

Interventions
MRI Scan of knee and knee arthroscopy

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Comparison of the proportion of arthroscopies (diagnostic or therapeutic) carried out in each arm of the study

Secondary outcome measures
1. A simple generic measure of health outcome. It allows an accurate self-description of current health related quality of life, assessing mobility, self-care, usual activity level, pain/discomfort and anxiety/depression.
2. Short Form health survey (SF36): a comprehensive generic measure of health outcome.
3. Knee injury and OsteoArthritis (OA) score: a self reported measure of symptoms, stiffness, pain, function and quality of life specific to knee injury.
4. Knee Society Score: will be carried out by a trained independent assessor (physiotherapist) who will be blinded to the management policy used.
5. Pain Severity
6. Patient satisfaction

Overall study start date
01/06/2001

Completion date
18/08/2006

Eligibility

Key inclusion criteria
1. Patients currently listed for arthroscopy or who have been admitted to hospital with an acute knee injury
2. Aged 18 years and above
3. Mechanical knee problem in whom an arthroscopy is indicated. Defined pragmatically as: suspected internal derangement of the knee e.g., cruciate/collateral ligament haemarthrosis (occurring in first 12 hours of injury) in the absence of fracture
4. Convincing symptoms but no signs, such as history of locking or giving way but normal exam
5. Unresolved significant symtoms after conservative treatment
6. Unresolved knee pain

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

384 (192 in each arm)

Key exclusion criteria
1. Multiple trauma
2. Unable or unwilling to give informed consent
3. Tumour
4. Suspected primary synovial disease
5. Previous arthroscopy of knee
6. Contraindications to MRI: e.g., pacemaker, pregnancy, ferric implants
7. Knee infection
8. Previous MRI of the affected knee

Date of first enrolment
01/06/2001

Date of final enrolment
18/08/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medical Research Unit
Stoke on Trent
United Kingdom
ST4 7QB

Sponsor information

Organisation
University Hospital of North Staffordshire (UK)

Sponsor details
Trust Headquarters
Royal Infirmary
Princes Road
Stoke on Trent
England
United Kingdom
ST4 7LN

Sponsor type

Hospital/treatment centre

Website
http://www.nsht.nhs.uk/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of North Staffordshire (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