Prognostic factors for cartilage degeneration in the knee after meniscectomy and cruciate ligament injuries. A prospective observational MRI cohort study

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Main Objectives1.To identify high risk patient groups for development of knee osteoarthritis (OA) in a cohort 9-10 years after meniscus, cruciate ligament and cartilage lesions.2.To determine the use of 3T MRI state of the art imaging in detecting...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON29928

Source
ToetsingOnline

Brief title
Prognostic factors for knee OA development.

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Cartilage degeneration, degenerative disease

Research involving
Human

Sponsors and support

Primary sponsor: Reumafonds
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: degenerative disease cartilage, knee complaints, OA, Osteoarthritis

Outcome measures

Primary outcome

Objective 1)

To identify high risk patient groups for development of knee osteoarthritis

(OA) in a cohort 9-10 years after meniscus, cruciate ligament and cartilage

lesions.

•Primary parameters: Kellgren-Lawrence Grading System for radiological OA of

the knee. The Altman score for radiological OA of the knee.

Objective 2)

To determine the use of 3T MRI state of the art imaging in detecting early OA

in the knee.

•Kellgren-Lawrence Grading System for radiological OA and the Altman score for

radiological OA of the knee compared to KOSS (Knee Osteoarthritis Score System)

grading for OA in MRI.

Objective 3)

To determine if functionality of the knee is affected by arthroscopic

intervention.

•Primary parameters: Noyes and Tegner questionnaires for functionality of the knee. KOSS (Knee Osteoarthritis Score System) grading for OA in MRI.

Objective 4)

To determine if genetic predisposition (hand OA, family history) is associated with development of OA of the knee.

•Primary parameters: DNA tests compared to the Kellgren-Lawrence Grading System for radiological OA and the Altman score for radiological OA of the knee

Secondary outcome

Objective 1)

To identify high risk patient groups for development of knee osteoarthritis (OA) in a cohort 9-10 years after meniscus, cruciate ligament and cartilage lesions.

•Secondary parameters: Knee injury and Osteoarthritis Outcome Score (KOOS), SF-36 generic health assessment questionnaire. Biomarkers in serum and urine: CTX-II, Glc-Gal-PYD, and PIIINP

Objective 2)

To determine the use of 3T MRI state of the art imaging in detecting early OA in the knee.

•Secondary parameters: KOSS (Knee Osteoarthritis Score System) grading for OA in MRI compared to the Knee injury and Osteoarthritis Outcome Score (KOOS).Objective 3)

To determine if functionality of the knee is affected by arthroscopic

intervention.

•Secondary parameters: Physical examination of instability, range of motion,

crepitus and signs of inflammation of the knee. SF-36 generic health assessment

questionnaire

Objective 4)

To determine if genetic predisposition (hand OA, family history) is associated

with development of OA of the knee.

•Secondary parameters: DNA tests compared to questionnaires for family history,

physical examination and X-ray of the hand.

Study description

Background summary

Osteoarthritis (OA) is a serious medical condition with considerable socio-economic impact. In the Netherlands more than ¤320 million are spent on treatment of such conditions per annum. The knee is affected in 350.000 (general practice, RIVM) to 1.400.000 (self reported in 25+ population, Picavet et al). Moreover, knee complaints are the third largest cause for work related problems of the locomotor system. Large prospective studies have confirmed knee trauma to be a significant risk factor for knee OA (Wilder 2002).
If sufficient data on patients would be available on occurrence and of progression of OA (e.g. ligament injury, obese, family, occupation etc), certain high-risk groups of patients could be distinguished. Not only could these patients benefit most from preventive measurements (i.e. exercise, chondroprotective agents, cartilage transplantation etc), but this would be cost-effective for society as well.

Method
The proposed study is based on a 1997 collected dataset of 859 patients. The latter study focused on the validity of MRI of the knee as a cost-effective tool to select patients who will benefit from arthroscopic treatment. These

patients had knee complaints more than four weeks. The knee complaints were clinically and radiologically evaluated. The average age was 31 years. Based on standard clinical assessment, patients were divided in two groups: Patients with high suspicion of intra-articular pathology requiring arthroscopic treatment and patients with low or absent suspicion of intra-articular pathology therefore not needing arthroscopic. MRI was performed by all patients.

Study objective

Main Objectives

1.To identify high risk patient groups for development of knee osteoarthritis (OA) in a cohort 9-10 years after meniscus, cruciate ligament and cartilage lesions.

2.To determine the use of 3T MRI state of the art imaging in detecting early OA in the knee.

3.To determine if functionality of the knee is affected by arthroscopic intervention.

4.To determine if genetic predisposition (hand OA, family history) is associated with occurrence and development of OA of the knee.

Study design

The proposed study is based on a 1997 collected dataset of 859 patients.The original data from history taking, physical examination, plain films, MRI and arthroscopy will be made available from the original database and incorporated in a new database.
All 859 patients are considered eligible for this study and will be recalled for follow-up. Patients are seen at the outpatient clinic of the department of Orthopaedic Surgery of the LUMC. Physical examination, plain films and MRI will be performed. Mouthswabs, blood and urine will be taken. The patients are asked to fill in three questionnaires.
In a second and last vist to the LUMC, MRI of the knee will be performed.

Study burden and risks

Two one hour visits to the LUMC.
Maximum time to complete the questionnaires at home: one hour.
Minimal X-ray exposure.
One venapunction

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participation in the study "MRI triage for arthroscopy" 1997.

Exclusion criteria

Pregnacy. Contraindications for MRI: pacemaker, implants etc.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2006
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13029.058.06