Identification of Early Osteoarthritic Changes of the Knee: Application of Novel Diagnostic Methods

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON35719

Source
ToetsingOnline

Brief title
early signs of osteoarthritis

Condition

- Tendon, ligament and cartilage disorders

Synonym
degenerative joint disease, osteoartritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: Anterior cruciate ligament rupture, early detection, follow-up, osteoarthritis knee

Outcome measures

Primary outcome

Degenerative changes in bone, cartilage and menisci evaluated by MRI, DXA scan,

radiographs and biomarkers.

Secondary outcome

not applicable

Study description

Background summary

Osteoarthritis (OA) is one of the most frequently occurring disorders of the locomotor system and a progressive disease leading to severe disability and pain. The risk of knee OA is extremely high after a rupture of the anterior cruciate ligament (ACL). So far, the pathophysiology of an ACL rupture leading to an evident radiologic knee OA remains unknown. Because of the incapability of radiographs to detect early degenerative changes, more sensitive tools are necessary to precisely monitor the pathophysiologic process of OA. In the present proposal we will focus on magnetic resonance imaging, DXA scan, bone shape modelling, and two biomarkers (CTX-II and osteocalcin).

Study objective

The aims of this research proposal are to detect; 1) which early (degenerative) changes occur in bone, cartilage and menisci in patients with an acute complete ACL rupture, 2) at what point of time after the initial injury do these early changes occur, 3) what is the cascade of changes in bone, cartilage and menisci in patients with an acute complete ACL rupture and 4) what are major predictors of these early changes?

Study design

In this study 160 patients with a complete ACL rupture will be included and prospectively evaluated 1 and 2 years after the initial trauma. To explore whether it would be worthwhile to evaluate the changes after a longer follow-up

period, additionally cross-sectional measurements will be performed in a group of 30 patients (4 years post-trauma).

Study burden and risks

A disadvantage for the participating patients is the additional time needed for the study during the outpatient clinic visits (approxiametely 1 hour), and two additional visits (after 1 and 2 year). Additional measurements at baselien are: DXA scan, questionnaires and blood and urine. Additional measurements at 1 and 2 years follow-up are: MRI, DXA scan, vragenlijsten questionnaires and blood and urine.

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

Patients aged between 18-40 years with a complete ACL rupture (diagnosed by MRI) will be included.

Exclusion criteria

Patients who do not speak the Dutch language; with initial trauma longer than 6 months ago; those with previous ACL injury, or meniscus, collateral ligament, cartilage damage (diagnosis by orthopedic surgeon); those with previous surgery of involved knee; those with disabling co-morbidity; and those with already osteoarthritic changes on MRI are excluded. Besides, those patients who do not want to be informed about unexpected findings will also be excluded.

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):	01-12-2008
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2008
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-06-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL21778.078.08