Early detection and monitoring of articular cartilage damage following knee trauma

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To identify intraarticular parameters related to the initiation and course of development of articular cartilage lesions after knee trauma.

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON34785

Source
ToetsingOnline

Brief title
Early detection of cartilage damage

Condition

- Joint disorders

Synonym
Cartilage damage, Focal cartilage lesion

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cartilage, dGEMRIC, Knee trauma

Outcome measures

Primary outcome

Primary endpoint will be the detection of development of an articular cartilage lesion at 12 months after trauma as detected by conventional MRI

The changes in intraarticular parameters (defined as the dGEMRIC value and synovial fluid cytokine concentration) within 4 weeks and at 4 months after trauma will be analyzed for their predictive value and/or causal role in the development of an articular cartilage defect 1 year after trauma (as determined from conventional MRI images by an experienced orthopaedic surgeon). Cytokine synovial fluid levels at 12 months will possibly reveal factors instrumental in maintenance or progression of the cartilage lesion at this time point.

Secondary outcome

Secondary endpoint parameters will be the relation between cytokine concentration (determined from synovial fluid) and cartilage quality (determined from the dGEMRIC values) and the relation between the clinical questionnaire scores on the one hand and cytokine concentrations and dGEMRIC values on the other hand.

Study description

Background summary

Articular cartilage damage is related to knee trauma, however it is unclear which factors initiate this process. Monitoring the changes during the process

from knee trauma to articular cartilage lesion and tissue disorganization, with subsequent degeneration, will unravel new prognostic factors and provide insight into those responsible for initiation and progression of disease, leading to future therapeutic targets to slow or reverse this degenerative process.

Study objective

To identify intraarticular parameters related to the initiation and course of development of articular cartilage lesions after knee trauma.

Study design

The proposed study is a prospective, explorative observational and etiological pilot study.
All included patients will receive a dGEMRIC MRI scan (an innovative measure of the proteoglycan content in articular cartilage) of their traumatic knee within 4 weeks after trauma and at 4 and 12 months after trauma. At the same time points we will also collect synovial fluid (by intra-articular aspiration after the dGEMRIC scan) from the traumatic knee for the biochemical analysis of cytokine levels and ask the patient to fill out the KOOS and Lysholm questionnaires and the VAS pain scale. At 12 months after trauma the patients will also receive a conventional MRI scan to analyze the presence of articular cartilage lesions.

Study burden and risks

Patients participating in this study will undergo 3 dGEMRIC scans of their knee. These scans will take about 30 minutes in total to perform. At 12 months after knee trauma each patient will receive an additional conventional MRI scan. Synovial fluid will be aspirated from the affected knee after the dGEMRIC scan. Next to this, patients will also be asked to fill out several questionnaires which will take around 15 minutes. Complications for both MRI and synovial fluid aspiration seldom occur.

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 older than 18 years of age
- Patients with an acute knee trauma with related effusion or haemarthrosis presenting at the emergency room or outpatient clinic.
See page 12 study protocol

Exclusion criteria

- Patients with knee effusion or haemarthrosis not related to trauma.
- Patients with an abnormal kidney function.
- Patients with a known anaphylactic response to Gadolinium or related substances.
- Risk groups for MRI scanning due to the magnetic field or contrast agent, like patients with pacemakers, nerve stimulators, metal particles, stents, clips or implants, (possible) pregnancy or who are breast feeding.
See study protocol page 12

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved

Date:	26-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL31357.041.10