Early detection and monitoring of articular cartilage damage following knee trauma

Published: 09-12-2008
Last updated: 06-05-2024

Primary Objective: To improve the detection of trauma related articular cartilage matrix damage by using a new contrast enhanced MRI technique.Secondary Objective(s): To evaluate the intraarticular changes (like proteoglycan content, disturbances in...

Ethical review	Not approved
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON32552

Source
ToetsingOnline

Brief title
Early detection of cartilage damage

Condition

- Tendon, ligament and cartilage disorders

Synonym
cartilage degeneration, Focal cartilage lesions

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, proteoglycan

Outcome measures

Primary outcome

Primary study parameter will be the change in dGEMRIC value at 4 and 12 months after the trauma as related to the first (<5 weeks after trauma) dGEMRIC scan.

Secondary outcome

Secondary parameters of this study will be the intraarticular changes after knee trauma as related to the clinical and functional condition of the patient (measured with specific questionnaires). We will use a correlation analysis to determine the association between the clinical condition of the patient and (changes in) cytokine spectrum, biomarkers and proteoglycan content (as parameters of cartilage quality)

Study description

Background summary

Knee trauma with subsequent hemarthrosis is related to damage of intraarticular structures, like articular cartilage. In addition, in vitro studies proved that high impact loading (f.e. during knee trauma) results in a significant proteoglycan loss from articular cartilage. These events are likely to induce a disturbance of joint homeostasis which enhances disease progression. Monitoring the changes occurring during the process from knee trauma to cartilage disorganization and subsequent damage would provide insight into the disease initiating factors and those with a progressive influence.

Study objective

Primary Objective:
To improve the detection of trauma related articular cartilage matrix damage by using a new contrast enhanced MRI technique.

Secondary Objective(s):
To evaluate the intraarticular changes (like proteoglycan content, disturbances in cytokine levels and biomarkers) after cartilage trauma to obtain an idea about the trauma related disorganization of the intraarticular environment as an initiating factor of cartilage damage and further degeneration

Study design

Prospective observational pilot study
All included patients will receive a dGEMRIC MRI scan of their traumatic knee within 5 weeks from trauma and at 4 and 12 months follow-up. At the same time points we will also collect synovial fluid from the traumatic knee (by intra-articular aspiration) and ask the patient to fill out the KOOS en VAS questionnaire.

Study burden and risks

Patients participating in this study will undergo 3 MRI scans of their knee with special dGEMRIC settings. Each scan will take about 30 minutes to perform. Synovial fluid will also be aspirated from the affected knee before each MRI scan is obtained. Next to this patients will also be asked to fill out several questionnaires (KOOS and VAS) which will take around 15 minutes. Complications for both MRI and synovial fluid aspiration seldom occur.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Patients must be older than 18 years of age.
-Patients must have an acute or recent (< 5 weeks old) knee trauma with hemarthrosis

Exclusion criteria

-Patients with diagnosed inflammatory rheumatic disease.
-Not trauma related hemathrosis.
-Contra-indications for gadolinium contrast MRI (abnormal kidney function)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

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

Ethics review

Not approved

Date:	09-12-2008
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	NL24908.041.08