Effects of osteotomies around the knee on cartilage glycosaminoglycan content using dGEMRIC non-invasive imaging

Published: 04-12-2007
Last updated: 10-05-2024

Primary objective: Evaluate changes in cartilage glycosaminoglycan content using dGEMRIC, in patients with osteoarthritis of the knee undergoing axial correction (HTO, femur osteotomy)Secondary objective: Correlate quantitative MRI data to...

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

Summary

ID

NL-OMON31458

Source
ToetsingOnline

Brief title
dGEMRIC and osteotomies

Condition

- Joint disorders

Synonym
joint degeneration, osteoarthritis

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, osteotomy

Outcome measures

Primary outcome

The measurement of the average T1-value will be performed measuring the distance from the location with the worst T1-signal to the center axis of the upper and lower limb. Further, changes in intensity of T1 signal will be measured to evaluate progression or decrease of cartilage damage.

Secondary outcome

Above mentioned outcomes will be correlated to questionnaires, measuring clinical effectiveness of the procedure (KOOS, VAS, Knee Society Scale).

Study description

Background summary

Medial compartment osteoarthritis (OA) of the knee is an invalidating disorder and leads to pain, decreased range of motion and inactivity. Underlying cause is degeneration- and subsequent loss of weight bearing capacity of knee cartilage. Two procedures aiming at maintaining original cartilage are the high tibial osteotomy (HTO) and the femur osteotomy. These procedures have proven to be effective in treating medial compartment OA of the knee in various clinical trials. However, effects of this procedure on cartilage quality are not known. Recently, a new technique has been developed which enables analysing changes in cartilage composition in vivo: the dGEMRIC. The dGEMRIC-technique is based on distribution of negatively charged contrast agent Gadolinium (Gd(DPTA)2) between the glycosaminoglycans in the knee cartilage. The T1-signal reflects the gadolinium uptake by the proteoglycans of the knee and thus provides us with an indicative parameter of the cartilage quality. Visualising changes in cartilage composition non-invasively will lead to greater understanding of the effect of such an operation on knee cartilage metabolism. Knowledge gained through the current pilotstudy can be applied in a study involving a greater number of patients.

Study objective

Primary objective: Evaluate changes in cartilage glycosaminoglycan content using dGEMRIC, in patients with osteoarthritis of the knee undergoing axial correction (HTO, femur osteotomy)
Secondary objective: Correlate quantitative MRI data to subjective symptom scores (KOOS, WOMAC, VAS, Knee Society Score)

Study design

All patients that are included in this study will receive their regularly planned operative treatment, as well as pre- and postoperative visits and radiographs. In addition, patients will receive an MRI scan with dGEMRIC settings before and 9 months after the surgical procedure, after removal of orthopaedic hardware. They will further receive questionnaires (VAS, WOMAC, KOOS, Knee Society Scale) before the surgical procedure and at 6,12, and 24 months after the surgical procedure.
The T1 values will be calculated as the average T1 signal of a region of interest (ROI) consisting of 40-60 pixels. These averages will be compared before and after treatment. Further, distances will be measured between center of biomechanical axis (using X-rays) and the center of worst affected ROI (on dGEMRIC). Also, associations of dGEMRIC scores (average T1 values) with KOOS, Knee Society and VAS scores will be analysed.

Study burden and risks

In addition to their regular treatment, patients participating in this study will undergo two MRI scans of their knee. Performing these scans will take about 4 hours in total. The second MRI scan will be performed 9 months after the initial operative procedure, after removal of orthopaedic hardware (procedure in daycare; burden: +/- 1 day).
Further, patients are asked to fill out questionnaires before- and after their surgical treatment. Filling out these questionnaires will take around 20 minutes per time moment (4 in total).
Risks associated with the MRI scan are the very infrequently occuring allergic reactions to the contrast agent, which is used to depict the cartilage. Risks related to removal of orthopaedic hardware are uncommon (infection, bleeding), as well as risks associated with anesthesia (allergic reaction, dental damage, paresthesia).

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

Osteoarthritis of the knee
Planned osteotomy above or below the knee

Exclusion criteria

Contra-indications for MRI scanning, using Gadolinium as a contrast agent

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-04-2008
Application type:	Amendment
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	NL18350.041.07