Assessment of Knee Cartilage Quality at 7T MRI with Glycosaminoglycan Chemical Exchange Saturation Transfer (gagCEST)

Published: 13-01-2016
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Validation of the gagCEST protocol with histology as golden standard. Detection of (or a reproducible gradation of) the cartilage defects based on the gagCEST MRI measurements for (early) diagnosis and monitoring of osteoarthritis.

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

Summary

ID

NL-OMON42475

Source
ToetsingOnline

Brief title
QUICK, QUantitative Imaging of Cartilage in the Knee

Condition

- Tendon, ligament and cartilage disorders

Synonym
cartilage degeneration, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 7T, cartilage, gagCEST, knee

Outcome measures

Primary outcome

Validation of the gagCEST protocol with histology as golden standard

Detection of (or a reproducible gradation of) the cartilage defects based on

the gagCEST MRI measurements for (early) diagnosis and monitoring of

osteoarthritis.

Secondary outcome

Relate the cartilage thickness on the clinically relevant morphological MRI

with the MTR asymmetry spectrum based on the gagCEST MRI.

Study description

Background summary

With our aging society, prevalence of degenerative diseases, like osteoarthritis (OA), has increased dramatically. Osteoarthritis is a degenerative joint disease, which mainly affects the articular cartilage. Osteoarthritis of the knee is one of five leading causes of disability among non-institutionalized adults and it leads to high costs for society: the estimated hospital expenditures in 2009 were 28.5 billion dollars and the job-related OA costs are estimated to 3.4 to 13.2 billion per year. In the Netherlands, almost 600.000 patients suffer from OA and 160.000 new cases are diagnosed every year. Since cartilage tissue has a limited ability to regenerate, early identification of cartilage damage improves chances of successful treatment and prognosis.

The gagCEST protocol is an emerging diagnostic technologies for cartilage defects. Previous in-house research showed promising results and we hope to extend this to clinical practice. The next step is a pilot study, to prove the clinical feasibility and added value of gagCEST on 7T MRI. The UMC Utrecht is one of the few hospitals in the Netherlands equipped with a 7T MRI and this study is using these facilities and their possibilities to its full extent, in

a way to provide better diagnosis and treatment monitoring for OA.

Nowadays, often an arthroscopy of the knee is used to assess the cartilage quality in patients with suspected cartilage damage or OA. We hope to replace the arthroscopy with a gagCEST MRI protocol. Therefore, this study will compare the cartilage scoring of a gagCEST protocol with the cartilage scoring of an arthroscopy.

Study objective

Validation of the gagCEST protocol with histology as golden standard. Detection of (or a reproducible gradation of) the cartilage defects based on the gagCEST MRI measurements for (early) diagnosis and monitoring of osteoarthritis.

Study design

This study is divided into two cohorts. For the first cohort (TKA cohort), patients from the department of orthopaedics who are scheduled to undergo a total knee arthroplasty (TKA) are included. These patients have severe cartilage damage and need a new knee. These patients will be recruited during outpatient clinic sessions or from the planned/scheduled operation list. The department of orthopaedics performs more than 100 TKA*s annually, which should be enough to recruit the number of patients required for this study.

The second cohort (arthroscopy cohort) includes patients from the department of orthopaedics who are scheduled for an arthroscopy because of suspected cartilage damage. These patient will be recruited during outpatient clinic sessions or from the planned/scheduled operation list. The department of orthopaedics performs more than 300 arthroscopies annually and this should be enough to recruit the number of patients required for this study.

This study is a single center pilot study, for which we aim to recruit 26 patients, 13 in both cohorts.

Study burden and risks

No extra risks involved.

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 who are planned to undergo a total knee arthroplasty because of severe cartilage damage or patients who are planned to undergo an arthroscopy because of suspected cartilage damage.

Exclusion criteria

Patients with previous knee surgery. Patients with other prostheses or metal objects/hardware. Patients with contra-indications to MRI scanning according to hospitals 7T MRI screening guideline of the UMC Utrecht

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):	08-03-2016
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2016
Application type:	First submission
Review commission:	METC NedMec

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	NL55298.041.15

Study results

Date completed:	01-08-2018
Results posted:	19-11-2020
Actual enrolment:	19

Summary results
Trial ended prematurely

First publication
26-10-2020