# 7T Sodium MRI of healthy and osteoarthritic cartilage of the knee

Published: 02-04-2014 Last updated: 22-04-2024

Goal of this study is to determine if high-field sodium-MRI can be used as:1) a sensitive, in vivo, and non-invasive biomarker to diagnose OA in an early stage and 2) as a method to follow the progression of OA and to monitor the effect of new...

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

# Summary

### ID

NL-OMON38455

**Source** ToetsingOnline

**Brief title** 7T sodium MRI of cartilage

### Condition

• Tendon, ligament and cartilage disorders

#### Synonym

degenerative joint disease, Osteoarthritis, wear and tear of the joint

#### **Research involving** Human

### **Sponsors and support**

Primary sponsor: Moleculaire Epidemiologie Source(s) of monetary or material Support: Reumafonds

### Intervention

Keyword: Biomarker, Cartilage, Osteoarthrosis, Sodium-MRI

### **Outcome measures**

#### **Primary outcome**

 A curve that describes normal sodium concentration in knee cartilage over a broad age range. This curve a a normal curve that can be used to detect early OA using sodium-MRI.

2) Fundamental insight into the mechanism of OA and cartilage degeneration by

comparing sodium concentrations in cartilage in different pools (bound to PG

and free in solution).

3) Development of a gold standard for sodium concentration measurements in vivo

in cartilage by comparing sodium-MRI with ex vivo concentration measurements of

post-surgery obtained cartilage.

#### Secondary outcome

If the primary outcomes are of sufficient quality then these techniques can be

used for the development of new OA treatments.

# **Study description**

#### **Background summary**

Osteoarthritis (OA) is a prevalent and disabling disease of the cartilage of the articular joints. Reliable indicators do not exist to diagnose or monitor changes of OA. Furthermore, there is no therapy available to cure OA or to slow the progression of the disease. The gold standard at this moment is the radiograph that can show OA, however this is at a late

stage of the disease where the damage to the cartilage is irreversible.

2 - 7T Sodium MRI of healthy and osteoarthritic cartilage of the knee 5-05-2025

Reliable biomarkers are necessary

for fundamental OA research and for the development and monitoring the effect of new treatments.

A strong candidate biomarker is sodium magnetic resonance imaging (MRI). Sodium is a building block of cartilage and is strongly linked to proteoglycan (PG) structures that determine the quality of cartilage. Changes in PG and subsequent "swelling" of cartilage are indicators of early OA. Using the high-field 7T MRI of the C.J. Gorter centre in the Radiology Department of the LUMC we can measure the sodium signal of cartilage in vivo.

### Study objective

Goal of this study is to determine if high-field sodium-MRI can be used as: 1) a sensitive, in vivo, and non-invasive biomarker to diagnose OA in an early stage and 2) as a method to follow the progression of OA and to monitor the effect of new treatments.

#### Study design

This research is a feasibility study to determine the possibility to use in vivo sodium-MRI of articular cartilage as a biomarker of OA and cartilage quality. The study was funded by the Dutch Reumafonds and is a "serendipity-project", indicating that is is a pilot study for which not much experimental work has been done but for which a theoretical basis exists.

The cartilage of patients who are undergoing knee prosthesis surgery due to OA will be analyzed with a biohistochemical sodium analysis such that pre-surgery sodium-MRI can be compared with post-operative ex vivo sodium concentration. By doing so, sodium-MRI can be directly related to a gold standard.

In addition to the patients a series of healthy volunteers (i.e. OA symptom-free) will be scanned using the same imaging protocol to determine a normal curve of sodium concentration in relation to age. Early detection of OA could be possible by comparing suspected patients to this curve.

#### Study burden and risks

Study participants will be in the 7T MRI scanner for a maximum duration of 60 minutes. After 30 minutes the knee coil will be placed around the other knee. The risk of this study is equal to the normal, low, risk of 7T MRI. It is important that the participants are screened for contra-indications for 7T MRI. There is no contrast agent administered, the participants have to tasks to perform other than to move as little as possible during scanning. The participant can listen to music during scanning.

# Contacts

**Public** Selecteer

Einthovenweg 20 Leiden 2333 ZC NL **Scientific** Selecteer

Einthovenweg 20 Leiden 2333 ZC NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

Patients: people who are selected for knee joint replacement Age-matched controls: people who are OA symptom free Healthy volunteers: people who are OA symptom free

### **Exclusion criteria**

Contra-indications for 7T MRI scanning No consent No family

# Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	31-10-2014
Enrollment:	200
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	02-04-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	24-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

# **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 CCMO **ID** NL45506.058.13