Distal radioulnar joint cartilage quantification at ultra high field 7T MRI

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

Summary

ID

NL-OMON40310

Source
ToetsingOnline

Brief title
Cartilage quantification at 7T MRI

Condition

- Other condition

Synonym
cartilage damage, osteoarthritis

Health condition

gewricht en kraakbeen

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: 7T MRI, Cartilage quantification, Distal radioulnar joint

Outcome measures

Primary outcome

Main study parameter/endpoint is the DRUJ cartilage quality. Healthy cartilage and injured cartilage will be compared on the 7T MR images, descriptively for morphology and quantitatively for composition.

Secondary outcome

Investigate the trend in correlation of qualitative imaging to:

- Pain.

- Disability.

- Range of motion.

- Healthy versus OA patients.

- Assess reproducibility in obtaining the quantified imaging parameters.

Study description

Background summary

The aim of the current feasibility study is to explore the possibilities of ultra high field 7Tesla (7T) MRI to quantify the distal radioulnar joint (DRUJ) cartilage quality. In the development and evaluation of cartilage repair techniques, non-invasive diagnostic tools to study cartilage quality in both a qualitative/ descriptive and in a quantitative way are essential. Qualitative study on cartilage quality describes the morphology. By quantifying the DRUJ cartilage, the composition of the cartilage can be determined. MRI at an ultra

high field strength of 7T is likely to be superior over high field 3T MRI for the quantification of DRUJ cartilage, by T2 mapping, T1rho, Diffusion-weighted imaging and gag-CEST for example. Advantages of 7T over 3T for these quantitative sequences are the higher distinctive capacity, the higher achievable signal to noise ratio (SNR), the higher spatial resolution and the more limited scan time. The higher SNR at 7T can be used to gain a better descriptive, morphological image of the DRUJ cartilage.
The hypothesis is that the morphology and composition of DRUJ cartilage can be assessed and quantified on ultra high field 7T MRI.

Study objective

The primary objective is to determine feasibility of DRUJ cartilage quantification on ultra high field strength 7T MRI by imaging healthy volunteers and OA patients. Feasibility means succesfull imaging DRUJ cartilage for all subjects. The two groups will undergo 7T MRI. The objective is to quantify DRUJ cartilage and compare results of all the 20 patients with cartilage damage to the results of the healthy cartilage of the volunteers. Quantitative and qualitative sequences will be used. Secondary objectives are applicable on qualitative imaging. Secondary objectives of the study are qualitative imaging performance and investigating trends in quantitative values with respect to pain, disability scores and range of motion. In addition, clinical modalities such as pain, disability and range of motion can be compared between the healthy volunteers and patients with damaged or OA cartilage. Data from literature are not useful to investigate the primary objective of this feasibility study and a power analysis cannot be done. The data now obtained could possibly be used as reference values for future research on the applications of cartilage restoration.

Study design

Feasibility study of observational research.

Study burden and risks

The patient group will undergo a 7T MRI scan in addition to the normal outpatient clinical routine.
The group of healthy volunteers will undergo history taking which consists of questions concerning the pain score, disability, occupation. They will also undergo a physical examination of the wrist which consists of determining the range of motion, an instability test, painful crepitus testing. Also they will have a 7T MRI scan.
A MRI scan is based on magnetism field and therefore undergoing a 7T MRI scan implies a negligible risk.

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

Volunteers:
Adults (> 18 years old) and mentally competent.
No ulnar sided wrist pain, previous surgery or trauma of the wrist.;Patients:
Adults (>18 years old) and mentally competent.
Symptomatic DRUJ complaints regarding cartilage damage, OA or pre-OA.
Patients that will undergo DRUJ replacement surgery (ulnar head prosthesis) or have DRUJ instability.

Exclusion criteria

o Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the

body that are not accepted for ultra high field strength MRI)
o <18 years old and mentally incompetent
o Previous wrist surgery
o Previous trauma (applicable to the volunteers group)
o Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2014
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	NL46783.041.13