Trapeziometacarpal Cartilage imaging in osteoarthritis: feasibility of 7 Tesla Magnetic Resonance Imaging and Optical Coherence Tomography

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To image cartilage of the TMC joint in patients with TMC OA by means of OCT and 7T MRI. To subsequently compare both methods to histopathology which will serve as a reference standard.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37270

Source
ToetsingOnline

Brief title
TMC Cartilage Imaging in osteoarthritis: feasibility of 7T MRI and OCT

Condition

- Joint disorders

Synonym
degenerative joint disease with loss of cartilage, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Plastische Chirurgie AMC

Intervention

Keyword: Cartilage imaging, MRI, OCT, Osteoarthritis

Outcome measures

Primary outcome

Visualization of TMC cartilage (degeneration) in advanced osteoarthritis using

7T MRI and OCT.

Secondary outcome

Secondary study parameters are (differences in) measured cartilage thickness,

cartilage volume/surface and surface fibrillation between OCT, 7T MRI and

histology.

Study description

Background summary

Osteoarthritis (OA) of the trapeziometacarpal (TMC) joint is an important cause of pain and disability, affecting a large number of patients in society. Diagnosis is usually made on clinical symptoms and the radiograph-based Eaton-Littler classification. Recent research has shown that the interobserver agreement between radiologists and hand surgeons concerning staging of TMC OA based on radiographs is moderate at best. The same was observed for case-specific treatment choices between hand surgeons. Moreover, it is known that the articular cartilage, which cannot be visualized on radiographs, is the primary location where changes in early OA occur. Consequently, diagnosis of TMC OA is frequently made in a more advanced stage of the disease, which often comprises irreversible damage to the affected joint, rendering reconstructive surgery necessary. Advances in OA imaging of the TMC joint are needed to ensure a more solid foundation for choosing a therapeutic strategy. This study investigates the feasibility of 7 Tesla Magnetic Resonance Imaging (7T MRI) and Optical Coherence Tomography (OCT) in TMC cartilage imaging in patients with known TMC OA, which will be correlated to histopathologic findings.

Study objective

To image cartilage of the TMC joint in patients with TMC OA by means of OCT and 7T MRI. To subsequently compare both methods to histopathology which will serve as a reference standard.

Study design

A prospective observational study

Study burden and risks

Participants are invited to undergo a pre-operative 7T MRI scan of the affected wrist at the University Medical Centrum Utrecht (UMCU), in addition to the routine clinical work-up. MRI research is regarded as safe, mild discomforts such as dizziness and nausea have been reported. During the scheduled arthroplasty procedure, the trapezium bone will be removed as part of the (normal) reconstructive procedure. Subsequently, the removed trapezium will be scanned using OCT and processed into histologic slides, for which informed consent will be required from the participating patients.

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

- Age 18 years or older
- Clinical symptoms of trapeziometacarpal osteoarthritis
- Patients is or will be scheduled for trapeziometacarpal joint arthroplasty
- Radiologic evidence for trapeziometacarpal osteoarthritis of at least stage 2 according to the Eaton-Littler classification

Exclusion criteria

- Not able to understand the written informed consent
- Contra-indications for MRI research
- Contraindications for surgery
- Under 18 years of age
- Radiologic evidence for TMC OA, of less than stage 2 according to the Eaton-Littler classification

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

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

Ethics review

Approved WMO Date:	07-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL42248.018.12