

Validation of MRI imaging of CMC1 osteoarthritis using histological characterization of involved tissues

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

Summary

ID

NL-OMON35705

Source

ToetsingOnline

Brief title

MR imaging of CMC1 osteoarthritis

Condition

- Tendon, ligament and cartilage disorders

Synonym

osteoarthritis, wear-and-tear of joints

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: CMC1 osteoarthritis, hand function, MRI imaging, validation

Outcome measures

Primary outcome

Index test: MRI

Reference test: histological characterization of bone, cartilage and synovial tissue

Secondary outcome

A number of characteristics thumb functioning such as strength, range of motion, coordination and the ability to perform daily life task with the hand.

Study description

Background summary

MRI imaging could optimise early detection of hand osteo-arthritis by depicting non-ossified structures such as cartilage, ligaments, synovial fluid, and peri-articular tendons. MRI imaging could therefore help to find etiological different subgroups and different stages of disease progression, supporting the development of new treatment regimes. This proposal is part of a series of projects to develop semi-quantitative and quantitative scoring systems with the aim of diagnosing different subgroups of osteo-arthritis and different stages of disease progression by MR imaging.

Study objective

The objective of the study is to determine the validity of MRI imaging to quantify changes in the CMC 1 joint in patients with osteoarthritis and how do these changes relate to functional status. The validity will be determined by comparison with findings during surgery and by histological characterization of bone, cartilage and synovial tissue obtained during surgery.

Study design

This is a cross-sectional diagnostic cohort study of 20 patients with hand

osteo-arthritis that are scheduled for surgical intervention. MR imaging will be compared to characterization of involved tissues such as cartilage, bone and synovial tissue. This tissue will be obtained during a surgical intervention (trapezectomy or joint replacement) that the patients are scheduled for. The operations that are performed are standard surgical interventions for hand osteo-arthritis. No additional surgical procedures are necessary to obtain the tissue needed to validate the MRI findings.

To compare MRI findings with observations during surgery, the surgeon will score quality of tissue (bone, cartilage, joint space, tendons) and shape of the tissue. In addition, a professional photographer will take images for post-surgery evaluation.

Study burden and risks

The chirurgical intervention is not adapted for this study and no additional interventions will be needed to obtain the tissue for histological characterization. The burden for the patients is mainly the three-hour duration of the study. The study includes MR imaging and a number of measures to determine the level of functioning of the hand. No risks have been reported for MR imaging and the hand function measures.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

CMC1 osteoarthritis patients scheduled for trapezectomy or joint replacement at the Erasmus MC.

Exclusion criteria

Patients will be excluded if they have any contra indications for MRI scanning, such as the presence of a pacemaker, metals in their body or pregnancy.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-04-2009

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date:	05-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	04-11-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	09-12-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL19114.078.07