Magnetic resonance imaging in early rheumatoid arthritis: The use of a 1.5T extremity scanner in early diagnosis

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Objective main studyObjectives to develop diagnostic and imaging tools to identify early RA-patients and stratify established RA-patients for individualized treatment strategies.Objective ultrasound study (amendment)-To compare inflammatory...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON41551

Source
ToetsingOnline

Brief title
Magnetic resonance imaging in early rheumatoid arthritis

Condition

- Joint disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: CTMM (CTMM-TRACER)

Intervention

Keyword: Diagnosis, MRI, Rheumatoid arthritis, Ultrasound substudy

Outcome measures

Primary outcome

Primary study parameters main study

- Presence of features of arthritis on MRI, correlated to clinical parameters

- Predictive value of MRI for development of RA

Primary study parameters ultrasound study (amendment)

- Presence of US inflammatory features correlated to MR detected (teno)

synovitis and clinical parameters.

Secondary outcome

Secundary parameters main study

- MRI findings in patients without RA but with an alternative diagnosis (e.g.

undifferentiated arthritis, psoriatic arthritis)

Study description

Background summary

Rheumatoid arthritis (RA) is a disorder leading to disability and serious loss of quality of life. Evidence is accumulating that postponing the onset and, in established RA, induction of drug free remission may be achieved if effective treatments are started in a timely manner in the individual patient. Hence, the ability to diagnose arthritis at an early stage and to apply the right medication at the right time in established RA is key to (cost) effective treatment of RA.

Study objective

Objective main study
Objectives to develop diagnostic and imaging tools to identify early RA-patients and stratify established RA-patients for individualized treatment strategies.

Objective ultrasound study (amendment)
-To compare inflammatory ultrasound findings to MR-detected (teno)synovitis of the hand and foot in patients with (early) RA.
-To identify (teno) synovitis in the hand and foot with US, to differentiate active from chronic tenosynovitis and to compare this to the MRI findings.

Study design

Study design main study
This is a longitudinal observational study. Patients referred to the LUMC early arthritis clinic that fulfill the inclusion criteria will have 1.5 Tesla (T) MRI of the (most painful or dominant) hand and foot at baseline. A patient friendly extremity scanner will be used. Those early arthritis patients with undifferentiated or rheumatoid arthritis will have repeated MR at 4, 8, 12 and 24 months. The 1.5T MRI will be performed using state of the art techniques, with intravenous contrast administration. Inclusion of patients will continue initially until a total sample size at baseline of 100 patients is reached. Follow up studies will be performed in two to three years. Results will be correlated with the final diagnosis and with clinical parameters obtained during routine patient care.

Study design ultrasound study (amendment)
All (early) RA patients who agreed to perform MRI of the hand and foot (baseline and follow-up) will be asked to undergo ultrasound of the hand and foot as well. The researcher performing US will be blinded to the MRI findings. A US protocol will be used to be able to compare to the RAMRIS score and established US7joint score. Grey scale and power doppler US will be performed. The presence or absence of synovitis will be determined in the four compartments of the wrist, the 5 MCP joints and PIP 2 and 3 joints (hand) and 5 MTP joints (foot)). Tenosynovitis will be determined in the flexor and extensor compartments of the wrist and flexor and extensor tendons at the level of the MCP joints (hand), and the flexor and extensor tendons of the MTP points (foot). With the use of color/power Doppler (PD US) the presence or absence of hypervascularisation will be evaluated. Examination time is approximately 15 minutes.
Inclusion initially will be 100 patients.

Study burden and risks

Risks main study
- Limited risk of contrast reactions or allergy (<1%).

Risks ultrasound study (amendment)
- None

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 referred with non-traumatic arthritis of at least one joint as confirmed by a medical doctor
- Duration of symptoms less than two years

Exclusion criteria

- Confirmed septic arthritis or crystal arthropathy
- Routine MRI-contraindications
- Pregnancy
- Renal insufficiency
- Gadolinium contrast allergy

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):	01-08-2010
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO

Date:	07-07-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-11-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-01-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	28-04-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	15-09-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL32390.058.10