Magnetic resonance imaging in early arthritis:
The use of a hand and foot MR scanner in early diagnosis of rheumatoid arthritis

Published: 02-11-2017
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To validate the findings on the diagnostic value of hand and foot MRI for early detection of RA in an independent sample set.

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

Summary

ID

NL-OMON52440

Source
ToetsingOnline

Brief title
Magnetic resonance imaging in early 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: ERC

Intervention

Keyword: Diagnosis, MRI, Rheumatoid arthritis

Outcome measures

Primary outcome

Predictive value of MRI for development of RA.

Secondary outcome

NA.

Study description

Background summary

Rheumatoid arthritis (RA) is a heterogeneous 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 the disease at an early stage is key to (cost) effective treatment of RA. In a previous study we studied the value of hand and foot MRI in early arthritis patients in the early detection of RA. We observed that MRI detected inflammation had an independent value. Replication of findings is essential and crucial to enhance the implementation of research findings in daily clinical practice.

Study objective

To validate the findings on the diagnostic value of hand and foot MRI for early detection of RA in an independent sample set.

Study design

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. The 1.5T MRI will be performed using state of the art techniques, with intravenous contrast administration. Inclusion of patients will continue until a total sample size at baseline of 550 patients is reached. The association between MRI abnormalities and the

final diagnosis will be determined.

Study burden and risks

Limited risk of contrast reactions or allergy (<1 %).

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):	03-11-2017
Enrollment:	550
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	06-05-2019
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-05-2022
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	ID
CCMO	NL63579.058.17