The effectivity of a short non-invasive fluid-sensitive MRI protocol to detect arthritis of hand joints: a comparative study

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To investigate the accuracy and effectivity of a short non-invasive fluid-sensitive MRI to identify clinical arthritis in patients with recent onset hand(s) complaints.The purpose of the *amendment* is to investigate in patients with joint...

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

Summary

ID

NL-OMON52073

Source
ToetsingOnline

Brief title
MRI in EARC

Condition

- Autoimmune disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: funding voor een PhD student door de Bontius Stichting

Intervention

Keyword: hand arthritis, MRI for subclinical joint inflammation

Outcome measures

Primary outcome

Clinically detectable arthritis (>=1 swollen hand joint) observed at physical examination by the rheumatologist in relation to MRI-detected joint inflammation.

With the portable MRI, joint inflammation imaged with the regular MRI is the outcome measure (in addition to the presence of joint inflammation during physical examination by the rheumatologist).

Secondary outcome

na

Study description

Background summary

Early detection of arthritis followed by early treatment is essential to improve the outcome of rheumatoid arthritis (RA)-patients and is the key of international guidelines for early arthritis. In practice however early recognition of arthritis is difficult. In the Netherlands, the majority of the delay is located at general practitioners (GPs). The gold standard for arthritis recognition is palpation of joint swelling at joint examination. At small joints arthritis is often subtle and GPs feel inexperienced in joint examination. To reduce referral delay and promote early recognition of arthritis, we initiated the Early Arthritis Recognition Clinic (EARC) in 2010. Although this is very effective in improving early recognition of arthritis, this initiative is (inter)nationally not widely implemented, presumably due to lack of rheumatologists/time. It would be more implementable if the joint examination by the rheumatologist could be replaced with an accurate device.

The last 10 years the departments of rheumatology & radiology have studied the value of MRI and shown that MRI is highly reproducible, sensitive, and specific. However its use is limited by its costs, need of contrast-enhancement and low accessibility due to the long scan protocol (~1 hour). Recently we have developed a short fluid-sensitive MRI protocol (scan time <5 min) that does not require contrast enhancement. This would make MRI patient-friendly, non-invasive, quick, and cheaper for early detection of arthritis. If accurate, it would allow implementation of MRI in clinical practice.
This short scan is made on the regularly used 3T scanners in the radiology department. These scanners are expensive (¤20 million) and heavy (2K kg) and are therefore only in hospitals. It is even more practical if a small portable MRI scan, specially developed for the hand, can be kept at/near the GP. Prof. Webb and his group at the LUMC have recently developed a portable brain scan that is considerably cheaper and lighter (costs ¤ 15,000, weight 60 kg). Hands can also be depicted with this. In an amendment we want to answer an additional research question, whether this portable scan can display joint inflammations as well as the "normal MRI". This analysis represents a first step in a trajectory that is aimed at developing an accurate MRI scanner that is practical for early recognition of arthritis in primary care.

Study objective

To investigate the accuracy and effectivity of a short non-invasive fluid-sensitive MRI to identify clinical arthritis in patients with recent onset hand(s) complaints.
The purpose of the *amendment* is to investigate in patients with joint inflammation whether the portable MRI can visualize this inflammation as well as the regular MRI.

Study design

This is a cross-sectional observational study.

Study burden and risks

In regular care the EARC comprises a short questionnaire and physical examination by the rheumatologist. In this study patients will also have an MRI-scan of the hands; this is a short protocol (<5 min) without contrast enhancement. Ideally this scan is made the same day, or alternatively within the same week. In case the MRI-scan is not scheduled the same day, an extra visit is necessary, which cost the patient more time. Patients will have no benefits when participating in this study. MRI will be scored blinded to clinical data. MRI results will not be communicated to rheumatologists or patients.
The portable MRI can be performed on the same day and the same hospital visit as the regular MRI. The portable MRI has a very low field strength, so there

are no risks involved. People sit on a chair next to the scan and put their hand in the MRI scanner during the scan. This scan is also performed blind to clinical data or imaging data obtained at the regular scan.

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 in whom GPs are uncertain of the presence of suspected arthritis and are referred to the EARC.
- Age >=18 years.
- Hand(s) complaints.
- Ability and willingness to give written informed consent and to comply with the requirements of the study protocol.

Exclusion criteria

- Contra indications for MRI: certain metal implants, pacemakers, pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-06-2021
Enrollment:	467
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-06-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-10-2024
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	NL75673.058.20