Identifying Rheumatoid Arthritis in the preclinical phase

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1) To study whether local inflammation is present in patients with Clinical Suspect Artralgia and detectable with dedicated extremity MRI2) To identify determinants (imaging but also serological, genetic factors) for progression to clinical...

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

Summary

ID

NL-OMON55369

Source
ToetsingOnline

Brief title
Identifying Rheumatoid Arthritis in the preclinical phase

Condition

- Autoimmune disorders

Synonym
inflammatory artralgia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: EU fonds en reumafonds

Intervention

Keyword: Artalgia, joint inflammation, MRI

Outcome measures

Primary outcome

Progression to clinical detectable arthritis and rheumatoid arthritis

Secondary outcome

-

Study description

Background summary

Studies on pathophysiological mechanisms involved in RA evaluate patients with clinical detectable arthritis. Also in our Leiden Early Arthritis Clinic/ *biobank reumatische ziekten* patients are included when arthritis of recent onset is present and patients are followed longitudinally. However, recent data suggest that disease processes can be active years before the development of clinically detectable arthritis. At present, not much is known on this preclinical phase. Joint pain of small joints of hands and feet that is of recent-onset and inflammatory in character is clinically suspect to become RA. In addition, it is known that an early initiation of treatment is most vital to improve the outcome of the disease. Early identification of the disease is key to early treatment initiation. The above mentioned data indicates that the disease starts perhaps preclinically. Therefore we want to study whether there is already local inflammation in the preclinical phase.
MRI is the most sensitive method to visualize such inflammation and will therefore be used in this study.

Study objective

1) To study whether local inflammation is present in patients with Clinical Suspect Artralgia and detectable with dedicated extremity MRI
2) To identify determinants (imaging but also serological, genetic factors) for progression to clinical arthritis

am 3: focus group
1) understanding of perceptions on different theme's from patients with atralgia of joints from the CSA-cohort by a focus group.

2) understandig if these perceptions are stable over time or if they change over 1 year.

amendment jan 2017:
Objectives

1) To study whether local inflammation is present in patients with Clinical Suspect Arthralgia and detectable with dedicated extremity MRI and ultrasound, and to study the course of subclinical inflammation over time.
2) To identify determinants (imaging but also serological, genetic factors) for progression to clinical arthritis
3) Evaluate the extent the symptoms influence the physical and mental well-being.

Study design

This study has a longitudinal design, but the majority of the follow-up is integrated in the already existing Leiden Early Arthritis Clinic/ biobank reumatische ziekten. Patients with Clinical Suspect Artralgia, identified via the Early Arthritis Recognition Clinic and via regular referrals, will be included. Data collected are questionnaires on joint symptoms and life style factors, a tender joint count, tubes with serum, PBMCs and DNA as well and a MRI of hand and wrist joints. Patients will be followed by their treating rheumatologist and research nurse and seen after 4, 13 and 25 months. As such general patients care will be combined with this observational study. In case of progression to clinically detectable arthritis, patients are included in the Early Arthritis Clinic cohort and follow-up in the Inflammatory Artralgia Cohort stops automatically. Patients in whom after 25 months no arthritis was detected, will be asked to have one MRI made and follow-up in the light of the Inflammatory Artralgia cohort will stop since we assume that the chance on progression later on is low.
The data collected will allow determining whether subclinical inflammation is preclinically present and if so whether inflammation in RA actually starts in the synovium (joint lining) or in the bone marrow. Finally it will allow studies on genetic and serological factors associated with progression to clinically detectable arthritis.

am 3: 8 patients from the CSA cohort will be asked to participate in the focus group with meetings on timepoint 0 and after 1 year. These meetings will take about 2 hour.

Amendment jan 2017, when the participants have an MRI (hand, feet), they also get an Echo (hand, feet).

Amendment juni 2021: due to logistical/study personnel reason there were no possiblities to perform an echo. In addition, the MRI scan on baseline will be performed conform standard care. Follow-up MRIs will be made for research

purposes. The MRI will take about 5 minutes and is without contrast. The study protocol and PIF have been adjusted for these changes.

Study burden and risks

The patients that will be followed in this study will be followed by their rheumatologist for general patient care. So the patients do not have to come to the hospital specifcally for the present study, but will be seen by their docter and also a research nurse.
However at baseline some data will be collected that is not part of routint patient care:
- filling in questionnaire on lifestyle factors
- additional tubes with blood will be taken (additional to general lab ordered by the rheumatologist)

Patients will have a MRI of hand joints. the MRI on the baseline visit will be perform conform standard care. Follow-up MRI's will be made for research purposes.

Blood is generally taken by the rheumatologist, though now additional blood will be collected.
The MRI is done and is generally safe.

amendment jan 2017, with the MRI also an Echo. The echo takes 20 minutes. There are no known adverse effects of the echo.

Amendment juni 2021: MRI length is shorter and without contrast. No echo will be performed. So less impact for the patient.

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

• Artralgia on hand or feet joints that is according to the rheumatologist clinical suspect to become RA (eg because of an inflammatory type or the presence of morning stiffness).
• Recent onset of complaints (< 1 year)
• Written informed consent

Healthy volunteers:
* no complaints of joints
*written informed consent

Exclusion criteria

• Arthritis at physical examination
• Known other conditions that may explain the pain or interfere with the evaluation of pain severity (e.g. osteoarthritis, gout, fibromyalgia)
• Patients with MRI-contraindications (e.g. instable metal implants, pacemaker/ICD, vascular clips, pregnancy).

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2012
Enrollment:	1060
Type:	Actual

Ethics review

Approved WMO

Date:	08-02-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-09-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-09-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	17-11-2014

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

Approved WMO Date:	02-02-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-08-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-07-2021
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	NL38832.058.11