Identifying Rheumatoid Arthritis in the preclinical phase

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Extension of the observational Leiden Clinically Suspect Arthralgia (CSA) cohort in the Medical Delta to enable sufficiently powered studies with the ultimate aim to arrive at proper accuracy to identify imminent Rheumatoid Arthritis.

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To study patients with clinically suspect arthralgia in order to 1) develop diagnostic/prognostic markers (a. markers of systemic and b. local inflammation as well as c. autoantibodies) for the development of RA 2) to improve the mechanistic...

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

Summary

ID

NL-OMON45509

Source
ToetsingOnline

Brief title
Identifying Rheumatoid Arthritis in the preclinical phase

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatoid arthritis

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: Arthralgia, Inflammation, Rheumatoid arthritis, Ultrasound

Outcome measures

Primary outcome

Clinical arthritis detected at physical examination by the rheumatologist,

persisting arthritis (present at two subsequent visits) or initiation of

treatment with Disease Modifying Anti-Rheumatic Drugs (DMARDs).

Secondary outcome

na

Study description

Background summary

At present, we cannot accurately identify patients with rheumatoid arthritis (RA) in the phase prior to clinically apparent arthritis. Measuring the three core processes of rheumatoid arthritis (auto-antibodies, local inflammation and systemic inflammation) serve well to identify RA patients in phases with clinical arthritis, yet are insufficient in pre-arthritis phases. An improved mechanistic understanding of these three processes will yield better biomarkers

to characterize RA before arthritis has become persistent. Furthermore, our comprehension of the mechanisms underlying progression from arthralgia to arthritis is limited as well as our understanding of patients* well-being in this phase.

Study objective

To study patients with clinically suspect arthralgia in order to 1) develop diagnostic/prognostic markers (a. markers of systemic and b. local inflammation as well as c. autoantibodies) for the development of RA 2) to improve the mechanistic understanding for progression from clinically suspect arthralgia (CSA) to RA and 3) to determine the physical and psychological well-being of patients with CSA during their disease course.

Study design

Observational cohort study.

Study burden and risks

In total, 4 visits will be scheduled in 24 months, or fewer in case patients develop arthritis or in case complaints spontaneously resolve. Visits as well as the collection of data will be integrated in regular patient care. Almost all data that will be collected in this study will come from measurements performed in regular patient care anyway (medical history taking, physical examination, radiographs of hands and feet, blood sampling). The only additional measurements are questionnaires, ultrasound of hands and feet, and additional blood samples (±80 ml).

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Arthralgia on hand, wrist or feet joints that is according to the rheumatologist clinical suspect to become RA (e.g. because of an inflammatory type or the presence of morning stiffness)
- Recent onset of complaints (< 1 year)
- Age > 18 years
- Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study as this precludes the presence of CSA:
- Presence of, or history of, clinically apparent arthritis
- Previous or current treatment with DMARDs or corticosteroids
- If another condition or explanation for the pain is more likely (other than imminent RA), a patient does not have CSA

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-05-2017
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	24-03-2017
Application type:	First submission
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	NL59939.078.16