Development of Tools (and prediction rules) to time and select therapy in treatment of pre-clinical, early and established Rheumatoid Arthritis: Creating Enhanced Remedy (TRACER): Very Early Rheumatoid Arthritis (VERA)

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to combine and validate diagnostic tests for the identification of preclinical very early RA (VERA) patients and prognostic tests for the prediction of progression

Ethical review	Approved WMO
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39332

Source
ToetsingOnline

Brief title
TRACER/VERA

Condition

- Autoimmune disorders
- Muscle disorders

Synonym
rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Center for Translational Molecular Medicine
Source(s) of monetary or material Support: Stichting: The Center of Translational and Molecular Medicine

Intervention

Keyword: arthralgia, arthritis, prediction, rheumatoid

Outcome measures

Primary outcome

Primary endpoint will be to develop a test or algorithm of multiple tests to

predict the development of RA in patients at risk.

Secondary outcome

Costeffectiveness of the (combination of) different tests compared to the

already existing tests, such as aCCP and RF.

Study description

Background summary

Rheumatoid arthritis (RA) is a heterogenous disease in which joint inflammation leads to structural irreversible joint damage, with as a consequence disability and serious loss of quality of life. Early timing of treatment is essential for the final outcome and therefore an early diagnosis is crucial.

Study objective

to combine and validate diagnostic tests for the identification of preclinical very early RA (VERA) patients and prognostic tests for the prediction of progression

Study design

We will conduct an observational study for 2 years.

Patients will be evaluated at 5 timepoints: at timepoint 0 , 6, 12, 18 and 24 months. At these timepoints a physical examination of the joints will be performed. Furthermore the patient will receive three questionnaires and blood will be drawn.
X-rays of hand and feet will be made at timepoint 0 and yearly after that.

Study burden and risks

Patient will be evaluated at 5 timepoints: at timepoint 0 and every 6 months thereafter up until 24 months. At these timepoints a physical examination of the joints will be performed. Furthermore the patient will receive three questionnaires. Furthermore information on life style (eg smoking), family history and current medication use will be gathered.
Blood will be drawn: at timepoint 0: 3 Paxgene tubes (each 2.5 ml), 1 coagulation tube (6 ml), 1 EDTA tube (6 ml) and 1 EDTA tube (5 ml), 2 heparinetubes (each 10 ml). At the other timepoints: 1 Paxgene tube (2.5 ml), 1 EDTA tube (5 ml) and 2 heparine tubes (each 10 ml). Apart from that, blood will be drawn for clinical purposes, such as ESR, blood count, CRP, aCCP and RF. Furthermore X-rays of hand and feet will be made at timepoint 0 and yearly after that, in accordance with clinical practice. Urine will be collected and stored. The burden of participation relies mainly on extra blood draws and filling in the questionnaires. Apart from possible small side effects of the blood draw, no risks are involved.
Patients do not directly benefit from participation. The benefit for the patient is an early diagnosis of RA.

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

- 18-70 yrs
- Arthralgia
- Rheumatoid factor or aCCP positive or a first degree relative with rheumatoid arthritis.

Exclusion criteria

- arthritis, established by a rheumatologist
- other cause for arthralgia, such as ostheoarthritis, metabolic syndromes etc.
- received treatment with Disease Modifying Anti Rheumatic drugs previously
- received prednisone treatment, except from cortical or intranasal application, in the last 6 weeks for inclusion.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO Date:	14-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL40652.041.12