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): early rheumatoid arthritis

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to combine and validate diagnostic and prognostic tests for patients with recently diagnosed rheumatoid arthritis to predict joint damage and response to (DMARD) therapy.

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

Summary

ID

NL-OMON39399

Source
ToetsingOnline

Brief title
TRACER/ERA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Centre of Translational Medicine
Source(s) of monetary or material Support: Centre of Translational and Molecular Medicine

Intervention

Keyword: arthritis, prognosis, rheumatoid, therapy

Outcome measures

Primary outcome

To test the predictive value of different tests, individually and combined, on

the prognosis and respons to therapy in early reumatoid arthritis patients.

- ACPA antibodies

- cytokine, chemokine, adipokine profiling

- (epi)genetic markers

Secondary outcome

Cost-effectiveness of these new tests and combinations of these tests to

predict prognosis and response to therapy compared to existing tests like RF.

Study description

Background summary

Rheumatoid arthritis (RA) is a heterogeneous disease in which joint inflammation leads to structural irreversible joint damage, with as a consequence disability and serious loss of quality of life. Early treatment has been shown to prevent or delay joint damage. However, which patients are at risk of developing joint damage remains largely unknown. Furthermore, up until now, no test is available to predict the response to different therapy strategies currently used in the treatment of rheumatoid arthritis.

Study objective

to combine and validate diagnostic and prognostic tests for patients with recently diagnosed rheumatoid arthritis to predict joint damage and response to (DMARD) therapy.

Study design

We will conduct an observational study for 2 years.
Patients will be evaluated at 3 time points: at baseline and at 12 and 24 months. At these time points a physical examination of the joints will be performed. Furthermore the patient will receive three questionnaires.
At each time point blood will be drawn for clinical purposes (daily practice), such as ESR, blood count, CRP, aCCP and RF (25 ml). For research purposes extra blood will be drawn: at time point 0: 3 Paxgene tubes (each 2.5 ml, for RNA), 2 coagulation tubes (10 ml, for serum), 1 EDTA tube (6 ml; for plasma) and 1 EDTA tube (10 ml, for DNA), 2 heparin tubes (each 10 ml, for PMBCs). Urine will be collected. At the other time points: 1 Paxgene tube (2.5 ml), 1 EDTA tube (5 ml), 1 coagulation tube (10 ml) and 2 heparine tubes (each 10 ml). Urine will be collected. Three questionnaires regarding their health and economic consequences of their disease will be filled in by patients at all three time points.

Study burden and risks

The burden of participation relies mainly on extra blood draws and filling in the questionnaires. The risk is considered minimal. Patients do not directly benefit from participation.

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

Recently diagnosed reumatoid arthritis patients who have not been treated yet with disease modifying antirheumatic drugs (DMARDs).

Exclusion criteria

- rheumatic disease, other than rheumatoid arthritis
- patients previously treated with DMARDs

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2013

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	27-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-05-2014
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	NL41029.041.12