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): established reumatoid arthritis

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to combine and validate diagnostic tests for the prediction of clinical response to therapy with biologics in patients with reumatoid artritis.

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

Summary

ID

NL-OMON39156

Source
ToetsingOnline

Brief title
TRACER/ESRA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatoid arthritis

Research involving

Human

Sponsors and support

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

Intervention

Keyword: arthritis, biological, prediction, rheumatoid

Outcome measures

Primary outcome

Response to treatment with biologics in patients with RA, based on EULAR and

ACR response criteria.

Prediction of response via in vitro assays

1) ACPA profiling

2) cytokine, chemokine and adipokine profiling

3) (epi) genetic profiling

Secondary outcome

Cost effectiveness of (combinations of) in vitro tests in predicting response

to biological treatment compared to existing tests such as RF and aCCP

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 prediction of clinical response to therapy with biologics in patients with reumatoid artritis.

Study design

We will conduct an observational study for 3-4 mo. Patients will be evaluated at 3 timepoints: at timepoint 0 and 3-6 weeks and 3-4 months after start with biological treatment. 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 (latter during routine visits).
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 timepoint 0: 2 Paxgene tubes (each 2.5 ml, for RNA), 1 coagulation tube (10 ml, for serum), 2 EDTA tubes (6 ml; for plasma and DNA), 2 heparinetubes (each 10 ml, for PMBCs). Urine will be collected. At the other timepoints: 1 Paxgene tube (2.5 ml), 1 EDTA tube (6 ml), 1 coagulation tube (10 ml) and 2 heparine tubes (each 10 ml). Urine will be collected.

Study burden and risks

Patient will be evaluated at 3 timepoints: At these timepoints a physical examination of the joints will be performed. Furthermore the patient will receive three questionnaires and blood will be drawn (+/_ 45 ml) timepoint. 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.

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 with established rheumatoid arthritis who are starting treatment with a biological (anti-TNFa, anti-IL-6, B cel inhibition or anti-costimulatory therapie)

Exclusion criteria

-patients with another rheumatological disease, that requires treatment with a biological

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):	06-02-2014
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	10-06-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-11-2015
Application type:	Amendment
Review commission:	METC NedMec

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	NL41030.041.12