Molecular Diagnostics in Rheumatoid Arthritis (MODIRA) cohort: Validation of predictive tools for prognosis and treatment strategies in rheumatoid arthritis, a multi-centre cohort study

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

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

Summary

ID

NL-OMON45651

Source
ToetsingOnline

Brief title
MODIRA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: AbbVie,Bristol-Myers Squibb,Pfizer,Sanquin ,UCB Pharma,ZonMW

Intervention

Keyword: biological, prediction, rheumatoid arthritis

Outcome measures

Primary outcome

Validation of prognostic tests, based on serological, cellular and molecular

markers, as well as several imaging techniques, to predict the response to

treatment and to predict disease severity and joint damage

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 6 months. Patients will be evaluated at 4 timepoints: at timepoint 0 and 4,16 and 26 weeks 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.
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.

Timepoint 0: 2 Paxgene tube (2.5 ml), 2 coagulation tubes (5 ml), 2 EDTA buizen (6 ml), 2 heparin tubes (10 ml).
Timepoint 4 en 14 weeks: 1 Paxgene tube (2.5 ml), 2 coagulation tubes (5 ml), 2 EDTA tubes (6 ml), 2 heparin tubes (10 ml).
Timepoint 26 weeks: 1 Paxgene tube (2.5 ml), 2 coagulation tubes (5 ml), 1 EDTA tube (6 ml)

Study burden and risks

Patient will be evaluated at 4 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

Public
Jan van Breemen Instituut

Dr. Jan van Breemenstraat 2

Amsterdam 1056 AB
NL
Scientific
Jan van Breemen Instituut

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
NL

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):	01-06-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL58582.048.16