

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

Published: 05-09-2016

Last updated: 10-08-2024

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	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 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 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 rheumatoid arthritis.

## 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 heparin tubes (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 heparin tubes (each 10 ml). Urine will be collected.

Timepoint 0: 2 Paxgene tube (2.5 ml), 2 coagulation tubes (5 ml), 2 EDTA tubes (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 cell 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

CCMO

### ID

NL58582.048.16