# Onderzoek naar het voorspellen van het effect van biologicals op de ziekteactiviteit van een individuele patiënt met reumatoïde artritis (RA)

Gepubliceerd: 17-06-2014 Laatst bijgewerkt: 19-03-2025

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON26414

**Bron**
NTR

**Verkorte titel**
BIO-TOP (Biologic Individual Optimized Treatment Outcome Prediction)

**Aandoening**

Rheumatoid arthritis. Biologics. Prediction. Ex-vivo cytokine profiling.

### Ondersteuning

**Primaire sponsor:** Sint Maartenskliniek Nijmegen
**Overige ondersteuning:** Sint Maartenskliniek Nijmegen

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Individual treatment response prediction based on the European League against Rheumatism (EULAR) good response criteria after 3 months of treatment with the biologic.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Background: Rheumatoid arthritis (RA) is characterized by heterogeneity in its clinical manifestations, pathological features and response to treatment. Clinical studies reveal that approximately 60% of RA a biologic as a predictor of individual treatment response after 3 months of treatment in RA patients. One of the determinants will be ex-vivo (un)stimulated and inhibited cytokine profiling, since this is in our view a promising candidate predictor and has not been investigated before
Objective: To investigate ex-vivo cytokine profiling and several other determinants (e.g. proteomics, genomics) before the start of treatment with abatacept, adalimumab, etanercept, rituximab and tocilizumab as a predictor of individual treatment response after 3 months of treatment in RA patients.
Study design: This is a prospective longitudinal prediction cohort study.
Study population: RA patients > 18 years, treated in the Sint Maartenskliniek (Nijmegen, The Netherlands), who are going to start with (or switch to) a biologic (including abatacept, adalimumab, etanercept, rituximab and tocilizumab) will be included in this study.
Method: At baseline (before start biologic), blood samples will be obtained from every patient. Ex-vivo cytokine profiling will be performed with specific cytokine-inducing stimuli, in the presence or absence of several concentrations of respectively abatacept, adalimumab, etanercept, rituximab and tocilizumab. Also, several other determinants (e.g. proteomics, genomics) will be investigated in the peripheral blood.
Main study endpoint: Primary outcome is the European League against Rheumatism (EULAR) good response criteria (DAS28CRP <3.2, and ΔDAS28CRP > 1.2 compared to baseline), 3 months after the start of treatment with one of the above biologics.

### Doel van het onderzoek

The objective of this study is to investigate ex-vivo cytokine profiling and several other determinants (e.g. proteomics, genomics) before the start of treatment with abatacept, adalimumab, etanercept, rituximab and tocilizumab as a predictor of individual treatment response after 3 months of treatment in RA patients.

### Onderzoeksopzet

Data will be recorded at baseline and after 3 and 6 months (+/- 1 month) of treatment with the biologic.

**Onderzoeksproduct en/of interventie**

The day of the first biologic administration is appointed as baseline.

At baseline (before start biologic), blood samples will be obtained from every patient. During follow-up, all patients will receive usual care and tight control.

In usual care, trained nurses assess the disease activity (DAS28CRP) during the outpatient clinic visits every 3 months (+/- 1 month). With these data, individual treatment response (EULAR good response criteria) can be calculated after 3 and 6 months (+/- 1 month) of treatment with the biologic.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Rheumatoid arthritis (either 2010 ACR RA and/or 1987 RA criteria and/or clinical diagnosis of the treating rheumatologist, fulfilled at any time point between start of the disease and

inclusion)

2. Patients with RA who start with (or switch to) biological therapy (including abatacept, adalimumab, etanercept, rituximab and tocilizumab)

3. Concomitant treatment with conventional DMARDs and/or NSAIDs is permitted

4. Age > 18 years

5. Informed consent

6. Ability to measure the study outcome in the patient (e.g. life expectancy >6 months, no planned relocation far away)

7. Ability to read and communicate well in Dutch

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 12-06-2014 |
| Aantal proefpersonen: | 400 |
| Type: | Werkelijke startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 17-06-2014 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41052
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL4405 |
| NTR-old | NTR4647 |
| CCMO | NL47946.091.14 |
| OMON | NL-OMON41052 |

## Resultaten

**Samenvatting resultaten**
https://pubmed.ncbi.nlm.nih.gov/30767874/