No registrations found.

Ethical review	Positive opinion
Status	Completed
Health condition type	-
Study type	Observational non invasive

Summary

Source

NTR

Brief title

BIO-TOP (Biologic Individual Optimized Treatment Outcome Prediction)

Health condition

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

Sponsors and support

Primary sponsor :	Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support :	Sint Maartenskliniek Nijmegen

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Response prediction based on the European League against Rheumatism (EULAR) response criteria after 6 months of treatment with the biologic.

2. Response prediction based on ΔDAS28CRP response criteria, after 3 and 6 months of treatment with the biologic.

3. Response prediction based on ACR/EULAR remission criteria, after 3 and 6 months of treatment with the biologic.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

None

Study design

Design

Study type :	Observational non invasive
Intervention model :	Other
Allocation :	Non controlled trial
Masking :	Open (masking not used)
Control :	N/A , unknown

Recruitment

NL

Recruitment status :	Completed
Start date (anticipated) :	12-06-2014
Enrollment :	400
Type :	Actual

IPD sharing statement

Plan to share IPD :	Yes

Ethics review

Positive opinion

Date :	17-06-2014
Application type :	First submission

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
NTR-new	NL4405
NTR-old	NTR4647
CCMO	NL47946.091.14 CCMO

Study results

Summary results

https://pubmed.ncbi.nlm.nih.gov/30767874/