Prediction of individual treatment response to biologics by ex-vivo immunological testing in rheumatoid arthritis

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To investigate ex-vivo cytokine profiling and several other determinants 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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41052

Source
ToetsingOnline

Brief title
BIO-TOP study: Biologic Individual Optimized Treatment Outcome Prediction

Condition

- Joint disorders

Synonym
chronic arthritis, RA, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: stichting Mycelium

Intervention

Keyword: biologics, prediction, rheumatoid arthritis, treatment outcome

Outcome measures

Primary outcome

Primary outcome is the European League against Rheumatism (EULAR) good response criteria (DAS28CRP <= 3.2, and *DAS28CRP > 1.2 compared to baseline), 3 months after the start of treatment with one of the above biologics.

Secondary outcome

Secondary outcomes include the *DAS28CRP compared to baseline and the ACR/EULAR remission criteria, 3 and 6 months after the start of treatment with one of the above biologics.

Study description

Background summary

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 patients do not achieve good clinical response after 6 months of treatment with a biologic. Moreover, individual treatment response cannot be predicted. Given the detrimental effects on quality of life and the destructive nature of RA, it would be desirable to predict, before the start of treatment, the (biologic) DMARD with the highest chance of good response in a RA patient. This would improve timely disease control. So far, studies have failed to consistently identify a single or set of biomarkers that can predict individual treatment response. In this study, we will investigate several determinants before the start of treatment with 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. In particular, performing ex-vivo cytokine profiling in blood samples inhibited by

a biologic seems promising, since this closely resembles the actual drug effect in RA patients.

Study objective

To investigate ex-vivo cytokine profiling and several other determinants 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 burden and risks

There will be minimal burden for the patients participating in this study, because blood samples will only be obtained at baseline. Moreover, measurement of the DAS28CRP is already performed in usual care, during the regular outpatient clinic visits every 3 months. The results of our study will have no direct implications for the treatment or prognosis of the individual patients, as the results of the baseline tests will be blinded until after treatment response is assessed.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574 NA
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574 NA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• 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)
• Patients with RA who start with (or switch to) a biologic (including abatacept, adalimumab, etanercept, rituximab and tocilizumab)
• Concomitant treatment with conventional DMARDs and/or NSAIDs is permitted
• Age >= 18 years
• Informed consent
• Ability to measure the study outcome in the patient (e.g. life expectancy >6 months, no planned relocation far away)
• Ability to read and communicate well in Dutch

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

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

Ethics review

Approved WMO Date:	30-04-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26414
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47946.091.14
OMON	NL-OMON26414