Potential optimalisation of (Expediency) and Effectiveness of TNF-blockers

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The primary goal of this study is to determine whether it is possible to discontinue treatment with TNF blocking therapy in patients suffering from RA when the patient has had stable low disease activity, without the occurence of an exacerbation.

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

Summary

ID

NL-OMON35995

Source
ToetsingOnline

Brief title
POET

Condition

- Autoimmune disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Eenmalige subsidiering door ministerie van Volksgezondheid Welzijn en Sport aan de Nederlandse Vereniging voor Reumatologie.

Intervention

Keyword: optimalisation, remission, safety of discontinuation of TNF blocker, TNF blocker

Outcome measures

Primary outcome

Primary outcome: the primary outcome measure is the percentage of patients who

experience an exacerbation of RA during the first year: increase of DAS28 >3.2

with a delta DAS28 of > 1.2.

Secondary outcome

Number of patients stopped anti-TNF at 12 months

Timespan of anti tNF usage, volume and medical costs

DAS28 value

Percentage of patients with a DAS28<3.2

Percentage of patients with a DAS28<2.6

Percentage of patients in remission according to ACR/EULAR criteria

Occurrence of side effects

Patient Satisfaction

Function (HAQ questionnaire)

Study description

Background summary

For the treatment of rheumatoid arthritis (RA) TNF blocking medication is very effective. TNF blocking medication, however, are relatively very expensive (1000 euro per month). Considering the chronic nature of RA patients are almost always treated by TNF blocking therapy for a long period of time. This longterm (*lifelong*) treatment entails two problems: longterm safety and

high costs for the Dutch healthcare budget.

Study objective

The primary goal of this study is to determine whether it is possible to discontinue treatment with TNF blocking therapy in patients suffering from RA when the patient has had stable low disease activity, without the occurence of an exacerbation.

Study design

The study design is an open label randomised controlled study design where patients are randomised to * discontinue TNF blocking therapy* or continue all anti-rheumatic medication including the TNF blocking therapy.

Study burden and risks

Except for the randomisation,no interference with the current care of patients with RA take place. Patients with RA will be seen by a rheumatologist and a nurse once every 3 months, as the CBO guideline advises. All measurements which are part of standard care will be performed every 3 months. Patients will be followed for a maximum of 2 years (end of study period). During each visit to the outpatient clinic blood will be drawn for the determination of inflammation parameters, which is also a part of standard care of RA-patients in the Netherlands.
Patient risks:
The discontinuation of TNF blocking therapy entails the risk that disease activity may rise. However, the study desing guarantees that at an exacerbation of disease activity (DAS28>3.2 PLUS Delta Das28>1,2, or DAS28>3.2 PLUS Delta DAS28>0,6 but <1.2 at 2 separate measurements with 2 to 3 month intervals) the same TNF-blocker can be restarted. If this happens in the control group the patient may switch to another treatment with a biological, as is also customary in usual care. The patients will be monitored frequently, by measuring the disease activity by means of the DAS28 so that in case of an exacerbation treatment can be adjusted swiflty. The risk of unnecessarily continuing TNF blocking therapy is an increased risk of malignities and infections.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Diagnosis Rheumatoid Arthritis according to the 1987 ACR criteria
•Treated for at least 1 year with a TNF-blocker and stable (no dose changes) DMARD treatment for the preceding 6 months
•Low disease activity for at least 6 months, according to both patient and rheumatologist, and a DAS28<3.2 measured at at least two different time points
•Signed informed consent.

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2012
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-07-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-04-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-01-2014

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

No registrations found.

In other registers

Register	ID
CCMO	NL36793.091.11