Potential Optimalisation of (Expediency) and Effectiveness of TNF-blockers.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22466

Source
Nationaal Trial Register

Brief title
POET

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: NVR
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the percentage of patients who experience an exacerbation of RA during the first year. Exacerbation is defined as a Disease Activity Score of 28 joint (DAS28) above 3.2 with a DAS28 increase of above 1.2

Secondary outcome

1. What is the difference between both groups in the proportion of patients who are treated with TNF blocking therapy after one year;

2. What is the difference in medical costs/effectiveness of stopping TNF blocking therapy versus continuing;

3. What is the difference between both groups in the DAS28, number of patients with a DAS28<2.6, number of patients in remission according to the ACR/EULAR criteria, at 3 months, at 6 months, at 9 months and at 12 months;

4. Is the treatment effect modified by disease duration, sex, smoking or anti-CCP;

5. In the stop group: How much time until restart of TNF blocking therapy;

6. In the stop group: Determining which (combination of) factors predict succesful stopping of TNF blocking therapy, defined as low disease activity without restart of TNF blocking therapy;

7. In the stop group: Determine whether the TNF blocking therapy is as effective after restart as it was before stopping TNF blocking therapy.

Study description

Background summary

Background:

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 system.

Goal:

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.

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. After having signed informed consent, patients with rheumatoid arthritis (RA) who are being treated with TNF blocking medication, are randomised to:

1. Discontinue the TNF blocking therapy and continuing all other anti-rheumatic medication or;

2. Continuing all anti-rheumatic medication including the TNF blocker.

Primary outcome:

The primary outcome measure is the percentage of patients who experience an exacerbation of RA during the first year. Exacerbation is defined as a Disease Activity Score of 28 joint (DAS28) above3.2. with a DAS28 increase of above 0.6.

Patients’ burden:

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.

Patients' risk:

The discontinuation of TNF blocking therapy entails the risk that disease activity may rise. However, the study design guarantees that at an exacerbation of disease activity (DAS28>3.2) PLUS Delta Das28>0.6) 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 swiftly. The risk of unnecessarily continuing TNF blocking therapy is an increased risk of malignities and infections.

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 Rheumatoid Arthritis when the patient has had stable low disease activity.

Study design

Interim reports every 3 months. Half way during the study and after the study intermediate and end report.

Intervention

666 patients stop their TNF blocking therapy, the other 333 continue.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis Rheumatoid Arthritis according to the 1987 ACR criteria;

2. At least 1 year of treatment with TNF blocking therapy and at least 6 months of stable DMARD treatment;

3. Low disease activity (DAS28<3.2 measured at least twice) for at least 6 months;

4. Signed informed consent.

Exclusion criteria

There are no exclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2011
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-10-2011
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	NL2965
NTR-old	NTR3112
Other	ZonMw : 152041001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A