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

Gepubliceerd: 21-10-2011 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22466

Bron
Nationaal Trial Register

Verkorte titel
POET

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: NVR
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Department of Rheumatology (470)

Radboud University Nijmegen Medical Centre
PObox 9101

P.L.C.M. Riel, van
Nijmegen 6500 HB
The Netherlands
+31-24-36-16531

Wetenschappelijk

Department of Rheumatology (470)
Radboud University Nijmegen Medical Centre
PObox 9101

P.L.C.M. Riel, van
Nijmegen 6500 HB
The Netherlands
+31-24-36-16531

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no exclusion criteria.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-10-2011
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2965
NTR-old	NTR3112
Ander register	ZonMw : 152041001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A