(English) Cost-effectiveness of new medicines (Mabthera and Orencia) compared to a second TNF blocking medicine, for patients with inadequate effect of a first TNF blocking medicine.

(Dutch)Onderzoek naar de kosteneffectiviteit van nieuwe medicijnen (Mabthera en Orencia) vergeleken met een tweede TNF blokerend middel, voor patienten met onvoldoende effect van een eerste behandeling met TNF blokkerende middelen.

Gepubliceerd: 24-12-2008 Laatst bijgewerkt: 18-08-2022

It is hypothesized that rituximab and abatacept are non-inferior alternatives to a second TNF alpha inhibiting therapy, for patients who have been adequately treated with a first TNF inhibiting therapy with insufficient effect.

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

Samenvatting

ID

NL-OMON26753

Bron
Nationaal Trial Register

Verkorte titel
Dutch Rheumatoid Arthritis Monitoring (DREAM) / Targeted Immune Modulator Evaluation (TIME) Trial

Aandoening

Rheumatoid Arthritis, Reumatoïde Artritis, cost-effectiveness, kosteneffectiviteit, doelmatigheid, daily clinical practice, dagelijkse klinische praktijk, biologicals, biologics, Targeted Immune Modulators, Rituximab, Abatacept, Adalimumab, Etanercept, Infliximab.

Ondersteuning

Primaire sponsor: Department of Rheumatology, University Medical Centre Sint Radboud
Overige ondersteuning: The Netherlands Organisation for Health Research and Development (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary clinical outcome is the mean of the DAS28 score measured at 6, 9 and 12 months follow-up. Furthermore costs (measured from a societal perspective), and quality adjusted life years (measured using utilities generated by the Euroqol 5D), over the first 12 months are additional primary outcomes.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective(s):

To compare the cost-effectiveness from a societal perspective of three treatment options, abatacept, rituximab or a anti-TNF alpha agent, for patients with rheumatoid arthritis who failed at least one anti-TNF alpha agent. Simultaneously, this study will provide data on the use of these medications in detail with regard to doses, frequencies and patient population in daily clinical practice.

Study design:

We propose, following upcoming guidelines about expensive inpatient pharmaceuticals, a pragmatic randomized trial. To prevent confounding by indication, all patients are being randomized to start treatment either with abatacept, rituximab or an anti TNF alpha agent. Thereafter, the treatment strategy will be at the discretion of the attending rheumatologist meaning that the rheumatologist is free to change treatment.

Study population:

patients are included in the study when the rheumatologist has the intention to change treatment because of failure on an anti-TNF alpha agent.

Intervention:

a treatment with abatacept, rituximab or an anti-TNF alpha agent.

Outcome measures:

Primary outcomes are the mean of the DAS28 score measured at 6, 9 and 12 months follow-up, quality adjusted life years and societal costs over 12 months.

Secondary outcomes are the health assessment questionnaire, the short-form 36, time to failure and the percentage of patients crossing over to another treatment.

Sample size calculation/data analysis:

Assuming a equivalence margin of 0.3 DAS28, 80% power and 10% drop-out, 87 patients are needed in each group to prove statistical equivalence between all treatment strategies. Analysis of covariance will be performed on all continuous outcome measures adjusting for baseline levels.

Economic evaluation:

Two types of incremental cost-effectiveness ratios will be calculated, namely the additional costs per point DAS28 reduction and the additional costs per QALY gained.

Time schedule:

This proposed study granted by ZonMw will then take place from January 2009 till December 2011. The one and a half year will be spend on an patients inclusion and data collection. Data collection will be proceeded for one other year. The last half year will be spend on data analysis and reporting of the results. At that time of analyses the minimum follow-up time will be 12 months and the maximum follow-up time will be two and a half years.

Doel van het onderzoek

It is hypothesized that rituximab and abatacept are non-inferior alternatives to a second TNF alpha inhibiting therapy, for patients who have been adequately treated with a first TNF inhibiting therapy with insufficient effect.

Onderzoeksopzet

Before the start of treatment patients will undergo a baseline assessment. According to daily clinical practice patients will be assessed each 3 months. Patients will be followed for a minimum of one year.

Onderzoeksproduct en/of interventie

After having signed an informed consent form, patients will be randomly assigned to either rituximab, abatacept or second TNF alpha blocking therapy. Further treatment decisions are at the rheumatologists descretion, following daily clinical practice.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. RA diagnosis according to ACR criteria;

2. Having been treated adequately with one of the anti-TNF alpha agents with insufficient effects;

3. A moderate to high disease activity (DAS28 > 3.2).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Former treatment with abatacept or rituximab;

2. Patient's or physician's preference for one of the agents;

3. Contraindications for the use of one of the agents.

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:	01-01-2009
Aantal proefpersonen:	132
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-12-2008
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	NL1535
NTR-old	NTR1605
Ander register	MEC/ABR/ZonMw : (2008/234)/NL24611.091.08/80-82310-98-09026
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten