(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.

No registrations found.

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

Summary

ID

NL-OMON26753

Source
Nationaal Trial Register

Brief title
Dutch Rheumatoid Arthritis Monitoring (DREAM) / Targeted Immune Modulator Evaluation (TIME) Trial

Health condition

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

Sponsors and support

Primary sponsor: Department of Rheumatology, University Medical Centre Sint Radboud
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (ZonMw)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

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):	01-01-2009
Enrollment:	132
Type:	Anticipated

Ethics review

Positive opinion

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

Study results