The cost-effectiveness of abatacept, rituximab or anti-TNF alpha for patients with rheumatoid arthritis

Published: 16-12-2008
Last updated: 06-05-2024

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…

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON32522

Source
ToetsingOnline

Brief title
The cost-effectiveness of three biological agents for RA patients

Condition

- Joint disorders

Synonym
reumatism, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMw,Abbott,Bristol-Myers Squibb,Hoffmann-La Roche,Schering-Plough,Wyeth

Intervention

Keyword: biologicals, costeffectiveness, daily clinical practice, rheumatoid arthritis

Outcome measures

Primary outcome

Primary outcomes are the DAS28 at 12 months, quality adjusted life years and societal costs over 12 months.

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

A direct comparison of the efficacy and medication costs as measured in controlled clinical trials (as often provided by the pharmaceutical companies) might be an invalid representation of the effectiveness and costs in daily clinical practice. To have the best balance between internal and external validity, we propose a pragmatic randomized trial. The results of such study could give valuable evidence for a common practice driven policy decision about the prescription of abatacept, rituximab or another TNF alpha blocking treatment for RA patients.

Study objective

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.

Intervention

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

Study burden and risks

because of the pragmatic design, patients are treated at the discretion of their own rheumatologist. According to the Dutch guidelines, a patients on a treatment with one of the biological agents should be monitored every three months on his/ her disease activity. Follow-up visits for this study will be planned on the same day as the visit at the out-patient clinic. For this study, additional questionaires have to be administered to measure functional ability (HAQ), quality of life (EQ-5d and SF-36) and the medical consumption.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) RA diagnosis according to ACR criteria
2) 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

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	261
Type:	Anticipated

Ethics review

Approved WMO Date:	16-12-2008
Application type:	First submission
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	NL24611.091.08