Long term prospective observational cohort study of the safety and efficacy of golimumab in the daily clinical practice of rheumatoid arthritis with emphasis on the lipid profile

Published: 16-02-2011
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To determinate the efficacy and safety of golimumab in rheumatoid arthritis patients in daily clinical practice during 48 months. In addition, the effect of treatment with golimumab on the lipid profile will be monitored during this study.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36406

Source
ToetsingOnline

Brief title
Golimumab in rheumatoid arthritis

Condition

- Autoimmune disorders
- Joint disorders

Synonym
inflammatory rheumatic disease

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Reade centrum voor revalidatie en reumatologie;voorheen Jan van Breemen Instituut

Intervention

Keyword: efficacy, golimumab, rheumatoid arthritis, safety

Outcome measures

Primary outcome

Efficacy will be determined in comparison to baseline by measuring disease

activity, radiological progression and functional capacity during follow-up.

Safety will be determined by the occurrence of side effects. Changes in lipid

profile markers during the four years of treatment will be analyzed versus

baseline.

Secondary outcome

nvt

Study description

Background summary

1) Golimumab, a TNF inhibitor, has recently been approved in the Netherlands for the treatment of moderate to severe rheumatoid arthritis. As efficacy in daily clinical practice can differ from the clinical (registration) trials, e.g. due to different patient groups, it is important to monitor the daily clinical practice.
2) Recently provisional evidence has been published for possible beneficial effects of TNF inhibitors on the prevention of cardiovascular disease, which might be mediated through modulation of the lipid profile.

Study objective

To determinate the efficacy and safety of golimumab in rheumatoid arthritis

patients in daily clinical practice during 48 months. In addition, the effect of treatment with golimumab on the lipid profile will be monitored during this study.

Study design

Prospective observational cohort study in patients in whom golimumab is started. Efficacy and safety data will be collected throughout the study. Lipid profiles will be compared to baseline

Study burden and risks

The additional *burden* consists of an extra blood sample taken at moments that this would already have been done in view of routine patient care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

patients with rheumatoid arthritis in whom golimumab treatment is started.
written informed consent.

Exclusion criteria

contraindications against golimumab treatment

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35215.048.11