# 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.

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|---|---|
| **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

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

Approved WMO

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|---|---|
| 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 |