

Prospective follow-up study of golimumab treatment in ankylosing spondylitis.

Published: 05-01-2012

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To determinate the efficacy and safety of golimumab in patients with ankylosing spondylitis in daily clinical practice prospectively. 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-OMON41382

Source

ToetsingOnline

Brief title

Golimumab in Bechterew

Condition

- Autoimmune disorders
- Joint disorders

Synonym

Ankylosing Spondylitis

Research involving

Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut

Source(s) of monetary or material Support: Reade centrum voor revalidatie en

Intervention

Keyword: Bechterew, efficacy, golimumab, safety

Outcome measures

Primary outcome

- ASAS20% response: When there is 20% improvement (and at least 10 points decrease on the 100mm VAS-scales) of at least three out of four domains of the following parameters: inflammation/morning stiffness (BASDAI), function (BASFI), pain (VAS) and patient global assessment (VAS), this therapy will be considered as effective.
- ASDAS improvement
- BASDAI 50 response

Secondary outcome

- the number of adverse events (infections, malignancies, mortality)
- improvement of mobility (BASMI)
- the peripheral joint swelling (44 joint count)
- the ESR and/or CRP
- the lipid profile
- the production of ANA
- relation between genetic polymorphisms and the efficacy of golimumab
- radiographic progression (conventional radiography, mSASSscore)
- occurrence of extraspinal manifestations (uveitis, colitis, cardiovascular events)

- changes in bone mineral density.

Study description

Background summary

1) Golimumab, a TNF inhibitor, has recently been approved in the Netherlands for the treatment of ankylosing spondylitis. 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, what may be mediated through modulation of the lipid profile

Study objective

To determinate the efficacy and safety of golimumab in patients with ankylosing spondylitis in daily clinical practice prospectively. In addition, the effect of treatment with golimumab on the lipid profile will be monitored during this study.

Study design

Propective observational cohort study in patients 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 ankylosing spondylitis 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): 30-03-2012

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 05-01-2012

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 20-02-2014

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 03-04-2015

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

CCMO

ID

NL39155.048.11