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

Published: 05-01-2012
Last updated: 01-05-2024

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

reumatologie;voorheen Jan van Breemen Instituut

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 differe 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 benificial 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

Prosepctive 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	ID
CCMO	NL39155.048.11