Prospective follow-up study of golimumab treatment in psoriatic arthritis

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

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

Summary

ID

NL-OMON37425

Source
ToetsingOnline

Brief title
Golimumab in psoriatic arthritis

Condition

- Autoimmune disorders
- Joint disorders
- Epidermal and dermal conditions

Synonym
psoriatic arthritis

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

Intervention

Keyword: efficacy, golimumab, psoriatic arthritis, safety

Outcome measures

Primary outcome

- ACR20 response: 20% improvement or 10 point decrease on 100mm VASscales

- PASI improvement

- MDA status

Secondary outcome

-The number of adverse events (infections, malignancies, mortality)

- LEI Improvement

-Number of digits with dactylitis

-Number of nails with nail psoriasis

-ESR and/or CRP

-The lipid profile

-inflammation processes

-Relation between genetic polymorphisms and the efficacy of golimumab

-Radiographic progression

-Changes in bone mineral density.

Study description

Background summary

1) Golimumab, a TNF inhibitor, has recently been approved in the Netherlands

for the traetment of psoriatic arthritis. 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 psoriatic arthritis in daily clinical practice prospectively. In addition, the effect of treatment with golimumab on the lipid profile will be monitored during this study and inflammation processes in the blood will be monitored.

Study design

Prospective 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 as well as the inflammation process in the blood.

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 psoriatic 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:	Pending
Start date (anticipated):	01-02-2012

Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	20-02-2012
Application type:	First submission
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	NL39474.048.12