Detection and evaluation of antibody formation against biologics in psoriasis

Published: 19-05-2010
Last updated: 11-05-2024

We would like to know to what extent psoriasis patients develop antibodies against biologics and what the clinical consequences of these antibodies are in routine practice.

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

Summary

ID

NL-OMON35618

Source
ToetsingOnline

Brief title
evaluation of antibody formation against biologics in psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: antibodies, biologics, psoriasis

Outcome measures

Primary outcome

The serum level of antibodies against the concerning biologic.

Secondary outcome

The disease severity objectivated by the PASI in patients with antibodies to

biologics compared to patients without antibodies to biologics at several

timepoints.

Study description

Background summary

Biologics are nowadays used in routine therapy for patients with moderate to severe chronic plaque type psoriasis. Registered (till 2009) are etanercept, infliximab, adalimumab and recently also ustekinumab. Except for ustekinumab, these biologics are also used in non-dermatological patients.
Experience with these patients showed that antibodies can be formed against the biologics. Antibody formation against the monoclonal antibodies infliximab and adalimumab has been shown to negatively influence the response to treatment in patients with ankylosing spondylitis, rheumatoid arthritis and Crohn*s disease. Also to the fusion protein etanercept antibodies are formed, although they do not seem to have a direct effect on the efficacy.
Since biologics have proven to be a valuable suppletion to the traditional therapeutic range for psoriasis, it is important to retain their efficacy.

Study objective

We would like to know to what extent psoriasis patients develop antibodies against biologics and what the clinical consequences of these antibodies are in routine practice.

Study design

This is a prospective observational cohort study.

The serum levels of the biologic and the serum levels of antibodies against the biologic concerned are measured at specific time points: week 0, week 12, week 24 and week 52. At the same time points disease severity is measured using the Psoriasis Area and Severity Index (PASI) and adverse events are evaluated.

Study burden and risks

At the timepoints week 12, week 24 and week 52 the routine blood drawing will have to be done at the moment the blood contains the lowest levels of the biologic and as a result the best measurable level of antibodies. For some patients this means they will have to postpone the administration of their drug for several hours, one day or several days until after the blood drawing. This depends on the frequence of administration, their usual moment for administration and the moment they visit the clinic. A patient can also choose to pay the hospital an extra visit for blood drawing just before they will administer the biologic. In that case they do not change their moment of administration and dose interval

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

- Written informed consent
- Patients diagnosed with chronic plaque type psoriasis
- Treatment with a biologic (etanercept, adalimumab, infliximab or efalizumab) for chronic moderate to severe plaque psoriasis started not longer than 52 weeks before.
- Consecutive patients starting treatment with a biologic (etanercept, adalimumab, infliximab or efalizumab) for chronic plaque psoriasis.

Exclusion criteria

- Previous treatment with the same biologic.
- Patients unable to comply with the requirements of the study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-06-2008
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO
Application type: First submission
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	NL23022.018.08