An observational study to investigate whether fatigue is a side effect of etanercept in patients with moderate to severe psoriasis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28989

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Fatigue (moeheid);

2. Psoriasis.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Dermatology
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The results of fatigue specific questionnaires.

Study description

Background summary

We have noticed that patients who are treated with etanercept for moderate to severe plaque type psoriasis remarkably often spontaneously report fatigue as adverse event . However, fatigue is not a known adverse event of etanercept and data in the literature are not univocal. Therefore, we have designed this pilot study to objectify whether fatigue is an adverse event of etanercept. Fatigue specific questionnaires are completed at week 0, week 6 and week 12 of treatment. At these moments blood and urine will be analysed to reveal some common disease that are known to cause fatigue. The same study procedures will be carried out in a comparable group of patients who start witj UVB therapy.

Study objective

Our hypothesis is that although treatment with etanercept improves the psoriasis and thereby the quality of lives in most people who are treated, in some people fatigue occurs as adverse event.

Intervention

None, this is an observational study.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients who start with etanercept or UVB therapy (control group) for psoriasis.

2. Patients who have a PASI > or = 10.

Exclusion criteria

1. Patients who have another active disease which is known to cause fatigue;

2. Patients who use therapeuticals which are known to cause fatigue;

3. Unability to comply with study procedures, like filling in questionnaires in Dutch.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2007

Application type: First submission

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
NTR-new	NL1042
NTR-old	NTR1075
Other	: incomplete
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A