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

Gepubliceerd: 19-09-2007 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28989

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

1. Fatigue (moeheid);

2. Psoriasis.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Dermatology
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The results of fatigue specific questionnaires.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

None, this is an observational study.

Contactpersonen

Publiek

Meibergdreef 9,
L.L.A. Lecluse
Amsterdam 1105 AZ
The Netherlands
++31 20 5662530

Wetenschappelijk

Meibergdreef 9,
L.L.A. Lecluse
Amsterdam 1105 AZ
The Netherlands
++31 20 5662530

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart

(Verwachte) startdatum:	30-10-2006
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1042
NTR-old	NTR1075
Ander register	: incomplete
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A