Efficacy of a novel experimental antibody in a humanized mouse model of psoriasis

Published: 12-01-2011
Last updated: 03-05-2024

In this study the efficacy of a novel monoclonal antibody on the development of psoriasis in the humanized mouse model will be investigated.This experimental compound will be compared with 2 registered drugs, i.e. Humira en Stelara.

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

Summary

ID

NL-OMON34037

Source
ToetsingOnline

Brief title
Monoclonal antibodies in psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
flaking disease, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: farmaceutisch bedrijf

Intervention

Keyword: compound, mouse, pre-clinical, psoriasis

Outcome measures

Primary outcome

The effect of treatment on the psoriatic process is tested by histological and immuno-histochemical techniques in the transplanted biopsies. The main read-out is epidermal thickness.

Secondary outcome

Serum markers in blood of transplanted mice will be studied together with markers on cultured cells from psoriasis patients.

Markers of inflammation in serum or RNA isolated from blood cells and in the skin.

Study description

Background summary

Psoriasis is a highly prevalent disease with great impact on the quality of life of the patients. Current treatments are far from ideal. The development of new compounds requires validation in an animal model, however, many differences exist between the skin of most animals and humans.
The department Biosciences at TNO has acquired expertise in the past year in transplanting human psoriasis skin onto a mouse. Thereby, we are able to perform pre-clinical testing of compounds for psoriasis. Non-laesional skin is transplanted onto a mouse and after engraftment injection with autologous T-cells synchronizes the psoriatic process.
Scientific background information can be read in Appendix 3. Since the study involves pre-clinical testing, patients will not experience a direct benefit from participation.

Study objective

In this study the efficacy of a novel monoclonal antibody on the development of

psoriasis in the humanized mouse model will be investigated.
This experimental compound will be compared with 2 registered drugs, i.e. Humira en Stelara.

Study design

A pharmaceutical company has asked TNO to test a potential new therapy for psoriasis in our humanized mouse model of psoriasis.
Besides animal welfare approval, we also need medical ethical clearance for obtaining skin biopsies and blood from psoriasis patients.
The skin will be transplanted onto mice after which autologous T-cells (isolated from the blood of patients) will be injected into the graft to synchronize development of psoriasis. As indicated in the study protocol (Appendix 1), 4 skin punch biopsies will be obtained from non-lesional skin along with 50 cc of blood.

Study burden and risks

TNO has arranged insurance for the patients participating in this study. However, medical risks are very low. A week after obtaining skin and blood samples, the stitches will be removed at the research center (PT&R) and a check will take place. With the consent of the patient, the medical practicioner of each patient will be notified about the participation.

Contacts

Public
Boehringer Ingelheim

175 Briar Ridge Rd
Ridgefield, CT 06877
US
Scientific
Boehringer Ingelheim

175 Briar Ridge Rd
Ridgefield, CT 06877
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Psoriasis patients: Adults (m/f) with a mild form of psoriasis vulgaris (PASI score of maximal 6). Patients are allowed to use local corticosteroids or ointments to prevent dry skin (see Appendix 2).

Exclusion criteria

Psoriasis patients: These patients have not received light therapy or another form of systemic treatment (methotrexate, cyclosporin A, anti-TNF treatments). Gender or age of the adults are not considered as exclusion criteria (see Appendix 2).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2011
Enrollment:	24

Type:	Actual

Ethics review

Approved WMO Date:	12-01-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL34992.028.10