Efficacy of a novel compound in a humanized mouse model of psoriasis

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In this study the effect of 1 novel compound on the development of psoriasis in the humanized mouse model isinvestigated. The efficacy is compared to a registered drug, Ustekinumab.

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

Summary

ID

NL-OMON37700

Source
ToetsingOnline

Brief title
Pre-clinical efficacy of a novel compound in psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
flaking disease, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: efficacy, mouse, Psoriasis

Outcome measures

Primary outcome

Effect on the psoriatic process is tested by histology and immuno-histochemical

techniques in the transplanted

biopsies. Main read-out is epidermal thickness.

Secondary outcome

Secretion of inflammatory mediators by cells from patients. Markers on cultured

cells from psoriasis patients. Possibly also inflammatory cells

in the skin tissue will be evaluated

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. TNO Life Sciences has acquired expertise in the past year in transplanting human psoriasis skin onto a mouse. Thereby, we are able to perform preclinical 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 effect of 1 novel compound on the development of psoriasis in

the humanized mouse model is
investigated. The efficacy is compared to a registered drug, Ustekinumab.

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 as well as 6 vials of
blood (ca. 8 ml each).

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 practitioner of each patient will be notified about the
participation.

Contacts

Public
TNO

Postbus 2215
2301 CE Leiden
NL
Scientific
TNO

Postbus 2215
2301 CE Leiden
NL

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

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 exclusion criteria (see Appendix 2).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2012
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO Date:	25-04-2012
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	NL40416.028.12