Efficacy of two proprietary compounds (D and E) in a humanized mouse model of psoriasis

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Test efficacy of compounds D+E in humanized mouse model of psoriasis.

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

Summary

ID

NL-OMON34058

Source
ToetsingOnline

Brief title
Pre-clinical efficacy of compounds D+ E in psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
flaking disease, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: TNO Kwaliteit van Leven
Source(s) of monetary or material Support: Farmaceutisch bedrijf

Intervention

Keyword: compound, mouse, pre-clinical, 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 epidermal thickness.

Secondary outcome

Serum markers in blood of transplanted mice will be studied together with

markers on culture cells from psoriasis patients. Possibly also inflammatory

marker in the tissue (skin) will be evaluated.

Study description

Background summary

Psoriasis is a highly prevalent disease which has great impact on the quality
of life of patients. Current treatments are far
from ideal. The development of new compounds requires validation in a animal
model, however many differences exsist
between the skin of most animals and humans.
The department of biosciences at TNO has acquired expertise in the past year in
transplanting human psoriasis skin on to
a mouse. Thereby, we are able to do pre-clinical testing of compounds for
psoriasis. Non-leasional skin is transplanted
after which injection with stimulated T cells induces the psoriatic process.
Scientific background information can be read in Appendix 3 &1 because this
study involves pre-clinical testing, patients
willnot experience a direct benifit from participation.

Study objective

Test efficacy of compounds D+E in humanized mouse model of psoriasis.

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 and blood from psoriasis
patients.
The skin will be transplanted onto mice after which blood cells will be injected into the graft to synchronize development of
psoriasis.
As indicated in the study protocol (appendix 1), 3 skin punch biopsies will be obtained from non-lesional skin as well as 4
vials of blood (+/- 10ml each).

Study burden and risks

TNO has arranged Insurance for the patients and healthy controls 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

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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 localcorticosteriods 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 (methotrexaat, cyclosporin A,anti-TNF treatments). Gender or age of the adults are not a 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:	Recruitment stopped
Start date (anticipated):	18-10-2010
Enrollment:	31

Type:	Actual

Ethics review

Approved WMO Date:	09-10-2010
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	NL33898.028.10