Efficacy of topical application of a proprietary compound Z in a humanized mouse model of psoriasis

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Is topical application of compound Z effective in reducing the development of psoriasis, induced in this humanized mouse model?

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

Summary

ID

NL-OMON32781

Source
ToetsingOnline

Brief title
Pre-clinical efficacy of compound Z 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: Bedrijf/Pharma

Intervention

Keyword: compound, mouse model, psoriasis

Outcome measures

Primary outcome

Efficacy of the therapy is tested by histology and immuno-histochemical

techniques in the transplanted biopsies.

Secondary outcome

Furthermore, the presence of compound Z will be evaluated in the skin after

treatment.

Study description

Background summary

Title: Efficacy of topical application of compound Z in a humanized mouse model of psoriasis.

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. Because this study involves pre-clinical testing, patients will not experience a direct benifit from participation.

Study objective

Is topical application of compound Z effective in reducing the development of

psoriasis, induced in this humanized mouse model?

Study design

A pharmceutical company has requested us to investigate a potential new therapy for psoriasis in our humanized mouse model. Besides animal welfare approval this study also requires approval of the medical ethics committee, as human skin biopsies are used. As indicated in the study protocol, 3 biopsies (of 6 mm in diameter) will be obtained from each patient together with 4 vials of 10cc of blood (appendix 1)

Biopsies of 22 of the 26 patients will be used to study the new therapy for the company (as mentioned in the study protocol). The biopsies from the remaining 4 patients will be used to study the effectiveness of another, beside betamethasone, known therapy, in this case topical application of vitamin D3. Herewith, it is our aim to further validate the model.

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

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):	01-03-2010
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2009
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	NL30767.028.09