

# Efficacy of a proprietary compound B in a humanized mouse model of psoriasis

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Test efficacy of compound B in humanized mouse model of psoriasis.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON34173

### Source

ToetsingOnline

### Brief title

Pre-clinical efficacy of compound B 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:** 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.

## 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 exist 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-leisional 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 will not experience a direct benefit from participation.

### Study objective

Test efficacy of compound B 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).

Additionally, the efficacy of a known topical treatment (calcipotriol) will be tested to further test the predictability of this mouse model.

### **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 practitioner of each patient will be notified about the participation.

## **Contacts**

### **Public**

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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 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 an exclusion criterion. (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): 01-07-2010

Enrollment: 26

Type: Actual

## Ethics review

Approved WMO

Date: 20-05-2010

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	NL32546.028.10