

# Single centre protocol for donation of skin tissue and blood samples by patients suffering from psoriasis vulgaris for efficacy testing of a novel treatment in animal studies

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Collection of skin tissue and blood samples from patients with mild to moderate psoriasis for efficacy testing of a new compound in a humanized mouse model.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON41795

### Source

ToetsingOnline

### Brief title

Donation of skin and blood by psoriasis patients for mouse studies

### Condition

- Other condition

### Synonym

Pre-clinical psoriasis research in laboratory mouse study

### Health condition

Donatie van weefsel voor proefdieronderzoek voor psoriasis (gehumaniseerd muismodel)

## Research involving

Human

## Sponsors and support

**Primary sponsor:** TNO Triskelion

**Source(s) of monetary or material Support:** TNO Triskelion

## Intervention

**Keyword:** Humanized mouse model, Psoriasis Vulgaris, Skin biopsy

## Outcome measures

### Primary outcome

Not applicable

### Secondary outcome

Not applicable

## Study description

### Background summary

Psoriasis is a highly prevalent disease (2-3% worldwide) with great impact on the quality of life of patients. Current treatments are suboptimal. The development of novel therapeutics requires validation in a preclinical animal model. Since the skin of most laboratory animals differs significantly from humans, a humanized mouse model for psoriasis can be applied to evaluate the efficacy of compounds to treat psoriasis vulgaris.

### Study objective

Collection of skin tissue and blood samples from patients with mild to moderate psoriasis for efficacy testing of a new compound in a humanized mouse model.

### Study design

Single-center study in the Netherlands

### Intervention

Collection of 40 mL blood and 4 skin biopsies

### **Study burden and risks**

- Blood samples will be collected via vena-puncture with possible risks of slight hemorrhages and bruising at the puncture site. Furthermore, the subject may faint or experience dizziness.

- Skin tissue will be collected via a skin biopsy procedure (under local anaesthesia) with the possible risks of mild pain, bleeding from the biopsy site, local reaction to the anesthetic and scar tissue formation. The risks are considered to be very low.

There is no direct benefit for the subjects participating in the study as the skin and blood samples will be collected for further use in animal studies, investigating new treatments for psoriasis vulgaris.

## **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

1. Written Informed Consent obtained
2. Suffering of mild to moderate psoriasis vulgaris, defined as a PASI score of 18 or less and a minimum of body surface index of 3% at Visit 1

### Exclusion criteria

1. Suffering from extensive psoriasis or having had non plaque or drug-induced forms of psoriasis
2. Undergoing light therapy or any systemic therapy
3. Diagnosis of a recent serious infection
4. A medical history of chronic or recurrent infectious disease

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 20

Type: Anticipated

## Ethics review

Approved WMO

Date: 25-02-2015

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	NL52298.028.15