

# The effect of INC1 and INC2 test compounds in the transplant model of psoriasis.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON45789

### Source

ToetsingOnline

### Brief title

Transplant model of psoriasis

### Condition

- Epidermal and dermal conditions

### Synonym

psoriasis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Derphartox

**Source(s) of monetary or material Support:** Farmaceutische industrie

## Intervention

**Keyword:** model, psoriasis, transplant

## Outcome measures

### Primary outcome

Effect on typical psoriasis skin features after treatment with INC1 and INC2 test compounds.

### Secondary outcome

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## Study description

### Background summary

Psoriasis is an autoimmune disease in which proinflammatory protein mediators, released by skin cells and infiltrating cells, cause abnormal cell division and cell differentiation. It may be possible to treat psoriasis using drugs aimed at preventing the synthesis of such mediators.

### Study objective

The aim of the project is to study the effect of INC1 and INC2 test compounds on typical features of the chronic disease psoriasis. This information can establish the most effective compound with the right formulation and dose for further research (e.g. in vitro, in vivo, clinical).

### Study design

Non-Lesional skin biopsies of 6 mm in diameter will be treated with INC1 and INC2 test compounds in the transplant model of psoriasis. By measuring the effect on typical psoriasis skin features, it is possible to establish the most effective compound with the right formulation and dose for further clinical research.

### Study burden and risks

The health risks associated with taking skin biopsies are small. It is possible

to obtain a slight scar formation and/or discolouration at the site of the biopsy punch.

## Contacts

### Public

Derphartox

Wytemaweg 80  
Rotterdam 3015 CN  
NL

### Scientific

Derphartox

Wytemaweg 80  
Rotterdam 3015 CN  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

Patients with moderate to severe psoriasis

### Exclusion criteria

Volunteers undergoing UV/light therapy or taking systemic drugs such as cyclosporin A or methotrexate

Volunteers using local topical corticosteroids  
Volunteers developing Köbner phenomenon at wound sites

## 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): 25-02-2019

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 17-12-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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

CCMO

### ID

NL68220.098.18