

# The effect of an antibody (Ab) against human IL-6 in the transplant model of psoriasis.

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To see if the new drug can prevent development of psoriatic changes in the transplant 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-OMON34138

### Source

ToetsingOnline

### Brief title

The effect of an Ab against IL-6 in the transplant model of psoriasis.

### Condition

- Autoimmune disorders
- Epidermal and dermal conditions

### Synonym

psoriasis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Argen-X

**Source(s) of monetary or material Support:** Argen-X

## Intervention

**Keyword:** blood, psoriasis, skin biopsies

## Outcome measures

### Primary outcome

NVT

### Secondary outcome

NVT

## Study description

### Background summary

5 mm skin bopsies, taken from non-involved skin of a psoriasis patient (volunteer), are transplanted onto immune-deficient mice . They are then injected with white blood cells from the same volunteer to induce the development of a psoriatic lesion in the transplant. A number of standard drugs have been shown to inhibit development of the psoriatic lesion, showing that the model is suitable for developing new drugs for treating psoriasis. Client wishes to test a novel drug in the transplant model.

### Study objective

To see if the new drug can prevent development of psoriatic changes in the transplant model of psoriasis

### Study design

3x5 mm skin biopsies and 27 ml blood will be taken from non-involved skin of 10 psoriasis patient (volunteer). The biopsy sites will be closed using 1 stitch. After 1 week the stitches will be removed. These materials will be used in the transplant model of psoriasis to test the new drug.

### Study burden and risks

The transplant model of psoriasis used is the only in vivo one available for evaluating the probable efficacy of new drugs to treat psoriasis. Donating skin biopsies is not perceived as being painful or taxing by the volunteers and they do not result in significant scarring. Donors consider the potential benefits in developing new therapies to more than compensate for any discomfort.

## Contacts

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Mild to moderate psoriasis vulgaris

## Exclusion criteria

Volunteers can not be taking drugs systemically, including immune-modifiers for other diseases.

Volunteers cannot be undergoing UV/light therapy

Volunteers should not show Kobner 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): 22-09-2010

Enrollment: 11

Type: Actual

## Ethics review

Approved WMO

Date: 09-08-2010

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**

<b>Register</b>	<b>ID</b>
CCMO	NL33124.098.10