

# Assessment of numbers and function of CD4+CD25+ regulatory T cells and Th17 cells in peripheral blood and lesional skin of patients with severe plaque-type psoriasis

Published: 24-04-2009

Last updated: 05-05-2024

The comparison of numbers and suppressive function of Treg in a population of severe psoriatic patients in peripheral blood by flowcytometry and the assessment of a Th17 (e.g. IL-17) cytokine profile from the supernatants. Furthermore, the relation...

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

## Summary

### ID

NL-OMON32455

### Source

ToetsingOnline

### Brief title

Treg/Th17

### Condition

- Autoimmune disorders
- Epidermal and dermal conditions

### Synonym

psoriasis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Dermatologie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** plaque psoriasis, regulatory T cells, Th17 differentiation

## Outcome measures

### Primary outcome

Numbers of Treg of severe psoriasis patients as compared to the results found in CMO study 2004/265.

Suppressive capacity of peripheral Treg of severe psoriatic patients as compared to CMO study 2004/265.

Describe the cytokine profile of Treg.

### Secondary outcome

Show the presence of Treg and Th17 cells in the skin by means of immunofluorescent investigation of skin biopsies, with emphasis on the Treg-Th17 interaction.

## Study description

### Background summary

Naturally occurring CD4+CD25+ regulatory T cells (Treg) are a distinct subtype of T cells with a suppressive function, by which these cell control effector T-cell activity. In psoriasis, the suppressive function of Treg is disturbed, leading to unrestrained T-cell proliferation and activity by which the chronic skin disease psoriasis is initiated and maintained. Furthermore, there is evidence for a prominent role of Th17 cells in the pathogenesis of psoriasis. The link between Treg and Th17 T cells has not yet been studied and is unclear.

### Study objective

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The comparison of numbers and suppressive function of Treg in a population of severe psoriatic patients in peripheral blood by flowcytometry and the assessment of a Th17 (e.g. IL-17) cytokine profile from the supernatants. Furthermore, the relation between Treg and Th17 cells will be studied in target tissue, in this case the skin, by means of immunofluorescence investigation.

## Study design

Cross-sectional pilot-study

## Study burden and risks

One visit in which peripheral blood and one 4 mm skin biopsy will be withdrawn. (30 mins)

## Contacts

### Public

Selecteer

René Descartesdreef 1  
6525 GL Nijmegen  
Nederland

### Scientific

Selecteer

René Descartesdreef 1  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Age >18

No successful systemic antipsoriatic treatment

Severe plaque-type psoriasis (Psoriasis Area and Severity Index (PASI) >10)

## Exclusion criteria

Other forms of psoriasis other than plaque-type psoriasis

Mild psoriasis

Age < 18

Concurrent systemic antipsoriatic treatment

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2009
Enrollment:	5
Type:	Actual

## Ethics review

Approved WMO

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Date:	24-04-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL26461.091.08