# Skin resident T cells in atopic dermatitis and psoriasis - Escape from regulation?

Published: 22-05-2007 Last updated: 10-08-2024

To determine the frequency and suppressive potential of skin resident regulatory T cells isolated from atopic dermatitis and psoriasis patients compared to healthy control subjects (the latter data will be obtained by co-workers at the Brigham and...

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeAllergic conditionsStudy typeObservational invasive

# **Summary**

## ID

NL-OMON31571

#### Source

**ToetsingOnline** 

#### **Brief title**

Skin resident T cells in atopic dermatitis and psoriasis

## **Condition**

- Allergic conditions
- Epidermal and dermal conditions

#### Synonym

atopic dermatitis, eczema

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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

### Intervention

**Keyword:** atopic dermatitis, psoriasis, regulatory T cells, skin

## **Outcome measures**

### **Primary outcome**

(a) Differences between the suppressive potential of skin resident regulatory T cells isolated from atopic dermatitis, psoriasis patients and healthy control subjects

(b) Differences between the the frequency of regulatory T cells in the skin of patients with atopic dermatitis, psoriasis and healthy control subjects.

## **Secondary outcome**

Not applicable.

# **Study description**

### **Background summary**

Atopic dermatitis (AD) is a common, itchy, chronic inflammatory skin disease. T cells have been suggested to play a critical role in the pathogenesis of AD, and lesional AD skin typically shows a striking infiltration of CD4+ T cells in the dermis and epidermis.

Regulatory T cells constitute a small proportion of CD4+ T cells, but have been shown pivotal for the suppression of immune responses. Recent, preliminary data have shown increased percentages of regulatory T cells in the skin of AD patients.

We therefore hypothesize that the chronic inflammation found in the skin of atopic dermatitis patients results from impairment of function of regulatory T cells.

After AD, psoriasis is the second most common skin disease, affecting approximately 2-3% of the population worldwide. Also in psoriasis, T cells are supposed to play a pivitol in the pathogenesis of the disease and regulatory T cells have been shown in psoriasis skin lesions.

## Study objective

To determine the frequency and suppressive potential of skin resident regulatory T cells isolated from atopic dermatitis and psoriasis patients compared to healthy control subjects (the latter data will be obtained by co-workers at the Brigham and Women's hospital).

## Study design

Observational study

## Study burden and risks

More detailed knowledge about the characteristics of skin resident regulatory T cells in AD and psoriasis will improve insights in the local inflammatory processes and may lead to the development of new therapeutic strategies. Skin biopsies are regularly taken in daily clinical practice and there are only minor risks associated with it. Although a rare complication, infection of the site of biopsy can be treated by the use of topical antibiotic ointments. The wound resulting from the biopsy may leave a hypopigmented (small) scar.

## **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**

- adult (18-70 years of age), male or female patients diagnosed with atopic dermatitis (diagnostic criteria as described by Williams), or (guttate or plaque) psoriasis
- biopsy location (about  $2x2\ cm$ ) should not be treated with topical steroids for at least  $1\ week$

## **Exclusion criteria**

- use of systemic immunosuppressive drugs (i.e., cyclosporin, prednisolone, methotrexate, neotigason, fumaric acid) in the 6 weeks prior to the inclusion
- exposure of biopsy location to (extraordinary) UV sunlight (i.e. UV-therapy, sunny holiday) in the 6 weeks prior to inclusion
- (secondary) skin infection

# 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: Recruitment stopped

Start date (anticipated): 29-05-2007

Enrollment: 48

Type: Actual

# **Ethics review**

Approved WMO

Date: 22-05-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 28-04-2008

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

# **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 NL15763.041.07