# Effect of inflammation on the stratum corneum lipid biosynthesis in the skin barrier of atopic eczema patients

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Determine the relationship between stratum corneum lipids (and their enzymes) and inflammatory markers in patients with AE. This is achieved by measuring:i) The SC lipid matrix and bound lipids, focussing on ceramides and its biosynthesis (i.e. the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

## Summary

## ID

NL-OMON42915

**Source** ToetsingOnline

**Brief title** SC lipids and inflammation in AE (EISBA)

## Condition

• Epidermal and dermal conditions

**Synonym** Atopic dermatitis, neurodermitis

**Research involving** Human

## **Sponsors and support**

Primary sponsor: Universiteit Leiden Source(s) of monetary or material Support: Ministerie van OC&W

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#### Intervention

Keyword: atopic eczema, inflammation, lipid biosynthesis, stratum corneum

#### **Outcome measures**

#### **Primary outcome**

To achieve our main objective of the study (Determine the relationship between stratum corneum lipids (and their enzymes) and inflammatory markers in patients with AE), analysis focuses on:

- Stratum corneum lipids

The SC lipid composition and SC bound lipids, focusing on ceramides and analysed by LC/MS

Local inflammatory markers and stratum corneum lipid enzymes
By means of two biopsies (per skin site), both local inflammation markers as
well as the protein expression and enzyme activity of key SC lipid biosynthesis
enzymes (e.g. GBA and aSMase) are analysed in situ by fluorescence microscopy

- Systemic inflammation markers

By means of a venepuncture, blood serum is obtained and levels of inflammatory markers are determined

- Skin barrier function

We analyze TEWL, as it is a common parameter that reflects the stratum corneum

barrier function.

#### Secondary outcome

- The skin pH, measured by skin pH-meter
- Local and total SCORAD, and EASI (both questionnaires)

# **Study description**

#### **Background summary**

De horny layer of the skin (stratum corneum) consists of dead skin cells surrounded by a lipid matrix. These lipids form a barrier: 1) it prevents excessive water loss (dehydration) from inside-out; 2) it prevents the penetration of exogenous compounds. In a previous study (p09.171), we demonstrated that patients with atopic eczema have a reduced skin barrier as a result of changes in the composition of the stratum corneum. Therefore, the skin of atopic eczema patients cannot maintain a normal water hydration level. In addition, it is expected that compounds (like irritants and allergens) can penetrate the skin more easily and cause an inflammatory response. This inflammation leads to red, dry and itchy skin. The previous study concluded that the level of changes in the skin barrier are strongly correlated to the altered stratum corneum lipids. At that time, we reported that future research should focus on 1) the cause of these changes in stratum corneum lipids (thus the enzymatic biosynthesis of the lipids); and 2) the role of inflammatory components for these changes in stratum corneum lipids. This is exactly what the new study addresses.

#### Study objective

Determine the relationship between stratum corneum lipids (and their enzymes) and inflammatory markers in patients with AE. This is achieved by measuring: i) The SC lipid matrix and bound lipids, focussing on ceramides and its biosynthesis (i.e. the expression and activity of enzymes related to the SC lipids).

ii) Local and systemic inflammatory markers.

ii) Transepidermal water loss (TEWL) levels: a common parameter reflecting SC barrier function.

#### Study design

Etiological case-control study that examines the relationship between SC lipids

(and their enzymes) and inflammatory markers in patients with atopic eczema.

#### Study burden and risks

The potential risk is minimal, and the obtained outcomes will lead to novel knowledge on atopic eczema. To relate the outcomes to the diseased state (atopic eczema) It is therefore necessary that we have to include AE patients as well as a control group

# 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**

(page 13 research protocol)

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- Aged between 18 and 40 years;
- Caucasian.

## **Exclusion criteria**

(page 14 research protocol)

- Aged under 18 or over 40;

- Non-Caucasian;
- Abundant hair presence on the ventral forearms;
- Unnatural abnormalities on one of their ventral forearms (e.g. skin lesions, tattoos);

- Using any systemic drug therapy (e.g. cholesterol-lowering drugs, insulin related drugs, steroids and immunosuppressants);

- Who received phototherapy in the past 2 years
- Pregnancy

Additional exclusion criteria for healthy subjects:

- No chronically inflammatory disease;
- Use of dermatological products (e.g. creams) on their ventral forearms on a daily basis.
- Dermatological disorders or a history of dermatological disorders

Additional exclusion criteria for AE patients:

- The absence of both lesional and non-lesional skin sites on their ventral forearms at day 0 of the study.

- The use of corticosteroids class IV or higher. Patients with corticosteroids class I-III need to give informed consent about changing their medication to a standardized regimen (see protocol page 11-13).

# 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

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Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	24
Туре:	Anticipated

## **Ethics review**

Approved WMO	
Date:	12-09-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## **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** NL57958.058.16