

# The effects of filaggrin deficiency on sensitization patterns, severity and quality of life in patients with atopic eczema

Published: 03-02-2012

Last updated: 29-04-2024

The objective of the study is mapping and assessing of the effects of filaggrin mutation on atopic eczema and other atopic diseases together with serological parameters.

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

## Summary

### ID

NL-OMON35846

### Source

ToetsingOnline

### Brief title

FILATOP

### Condition

- Epidermal and dermal conditions

### Synonym

dermatitis, eczema

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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

## Intervention

**Keyword:** Atopic eczema, Filaggrin, Raman, Sensitation

## Outcome measures

### Primary outcome

Main study parameter is the prevalence of sensitisation to specific inhalant allergens in correlation to filaggrin deficiency.

### Secondary outcome

Secondary study parameters are the scores on symptom based and quality of life questionnaires and Raman-spectral variations, reflecting variations in molecular composition of the skin in AD.

## Study description

### Background summary

Filaggrin (FLG) deficiency is a key player in the pathogenesis of atopic diseases. It is the strongest risk factor known to date for atopic dermatitis and associated atopic march and disease specific symptoms like itch. Evidence is building up that filaggrin deficiency causes a primary breakdown in the epidermal barrier, which is the initial event in the development of atopic dermatitis. Our understanding of gene- environment interactions, as the initial event in the development of AD, should lead to a better use of some topical products, avoidance of others, and the increased use and development of products that can repair the skin barrier. No direct link has been made between filaggrin deficiency and specific inhalant sensitization, itch and quality of life before.

### Study objective

The objective of the study is mapping and assessing of the effects of filaggrin mutation on atopic eczema and other atopic diseases together with serological parameters.

### Study design

The study is designed as an exploratory cohort study in which patients with atopic eczema deficient in filaggrin are compared to patients with atopic eczema with sufficient levels of filaggrin.

### **Study burden and risks**

No benefits are to be expected for the individual subjects in this study. The risks following procedures in this study are comparable to risks the patients are exposed to during routine care for atopic eczema.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Burg. s" Jacobplein 51  
3000 NL  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Burg. s" Jacobplein 51  
3000 NL  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Patient has been diagnosed with atopic eczema by attending dermatologist

## Exclusion criteria

Patient is not willing to participate  
Patient does not speak or read Dutch  
Patient is younger than 18 years of age  
Patient can not be instructed

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2011

Enrollment: 100

Type: Anticipated

## Ethics review

Approved WMO

Date: 03-02-2012

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL36515.078.11