

# Histological and pathophysiological investigation of hyperkeratotic hand eczema

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To compare histopathology and immunofluorescence expression of keratins, epidermal barrier proteins and adhesion molecules in hyperkeratotic hand eczema (lesional skin) and non lesional skin of the palms in patients, compared to healthy individuals...

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

## Summary

### ID

NL-OMON45756

### Source

ToetsingOnline

### Brief title

Histologically and pathophysiology of hyperkeratotic hand eczema

### Condition

- Epidermal and dermal conditions

### Synonym

eczema hyperkeratoticum et rhagadiforme, hyperkeratotic hand eczema

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Het onderzoek is investigator-initiated en wordt gefinancierd vanuit de onderzoekslijn eczeem en contact allergieën.

## Intervention

**Keyword:** Histological, hyperkeratotic hand eczema, pathophysiological

## Outcome measures

### Primary outcome

To compare the immunofluorescence profile of different keratin proteins, epidermal barrier proteins and adhesion molecules in the skin of patients with hyperkeratotic hand eczema with healthy controls

### Secondary outcome

- To compare lesional with non lesional skin of the palms of hyperkeratotic hand eczema patients
- To describe the histopathology of hyperkeratotic hand eczema
- To describe the ultrastructure and expression of desmosomal components of hyperkeratotic hand eczema compared to healthy controls

## Study description

### Background summary

Hand eczema is a common skin disease with a high socioeconomic impact. It has an estimated 1-year prevalence of up to 10% and is considered to be the most common occupational skin disease, leading to prolonged sick leave or a change of job. It has also a high burden of disease due to the visibility and the social importance of the hands. Different hand eczema subtypes exist. Hyperkeratotic hand eczema is a well characterized morphological subtype of hand eczema. Typical are sharply demarcated areas of hyperkeratosis on the palms (and frequently on the soles), as are painful fissures. Vesicles are absent. The pathophysiology of hyperkeratotic palmar eczema has not been elucidated.

### Study objective

To compare histopathology and immunofluorescence expression of keratins,

epidermal barrier proteins and adhesion molecules in hyperkeratotic hand eczema (lesional skin) and non lesional skin of the palms in patients, compared to healthy individuals.

## **Study design**

Observational case control study

## **Study burden and risks**

Skin of healthy volunteers and patients with hyperkeratotic hand eczema will be obtained by punch biopsies under local anesthesia. It is a generally safe procedure with minimal burden to the patient. Possible complications of bruising, bleeding, infection and scarring rarely occur. Both participants in the case group and participants in the control group need to visit only once. Patients will be compensated for their costs and will additionally receive a compensation for participating in the study.

## **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

- Written informed consent.
- $\geq 18$  years old.
- Hyperkeratotic hand eczema as defined by the Danish Contact Dermatitis Group
- No concomitant diagnose of atopic dermatitis (current)

### Exclusion criteria

- Immunosuppressive or immunomodulatory treatment within the last 4 weeks
- UV radiation therapy within 4 weeks before biopsy
- Active bacterial, fungal or viral infection of the hands
- Other skin diseases of the hands
- Proven contact sensitization with clinical relevance to the hands, in which exposure to allergens is not avoided
- History of psoriasis or psoriasis lesions elsewhere on the body

## 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):	08-06-2018
Enrollment:	12
Type:	Actual

## Ethics review

Approved WMO	
Date:	15-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL65563.042.18