

Histology, transcriptome and microbiome of vesicular hand eczema - an explorative pilot study.

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Objective: To compare histology, gene expression profile (using transcriptome analysis and quantitative Polymerase Chain Reaction (qPCR) validation) and the microbiome of vesicular endogenous hand eczema between and within patients and to skin of...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON46554

Source

ToetsingOnline

Brief title

Histology, transcriptome and microbiome of vesicular hand eczema

Condition

- Epidermal and dermal conditions

Synonym

hand dermatitis, Hand eczema

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: J.P. Naterfonds

Intervention

Keyword: Hand eczema, Histology, Transcriptome, Vesicular

Outcome measures

Primary outcome

To compare the gene expression profile of vesicular endogenous hand eczema (using transcriptome data and validation with quantitative Polymerase Chain Reaction (qPCR)) in non-lesional and early vesicular skin between and within cases and to healthy controls.

Secondary outcome

- Protein expression: to further explore the findings from transcriptome analysis in immunohistochemistry experiments on skin taken from patients with vesicular endogenous hand eczema and healthy controls.
- To compare histologic morphology of vesicular endogenous hand eczema between and within cases and to healthy controls.
- To compare microbiome colonization profile between and within cases and to healthy controls.

Study description

Background summary

Rationale: Hand eczema is a common disease. Many studies on its treatment have been carried out. Remarkably, surprisingly little research has been done on its pathogenesis. More insight into the disease on a more fundamental level should lead to a better understanding of the biological processes involved, as well as new avenues for the development of treatment strategies. The subtype of vesicular endogenous hand eczema is well characterized and grants the opportunity to follow the development of disease morphology quite clearly.

Study objective

Objective: To compare histology, gene expression profile (using transcriptome analysis and quantitative Polymerase Chain Reaction (qPCR) validation) and the microbiome of vesicular endogenous hand eczema between and within patients and to skin of healthy controls.

Study design

Study design: Observational case-control study.

Method: From cases, two five-millimetre skin punch biopsy samples will be collected during the course of one vesicular hand eczema episode: (1) non-lesional skin; (2) skin with visible vesicles, but without other signs of inflammation. From controls, one five-millimetre skin punch biopsy sample will be collected from the hypothenar region of the non-dominant hand. Also, swabs will be taken from the palms of the hands of subject with hand eczema and healthy subjects.

Study burden and risks

Both participants in the case group and participants in the control group need to visit only once. Skin biopsies will be performed. This is a standard dermatological procedure, performed on a daily base. It is a generally safe procedure with minimal burden to the patient. Biopsies can be mainly associated with a small risk of scarring, prolonged bleeding and/or infection.

Furthermore, photographs will be taken of the participants hands before taking the skin biopsy. This poses no extra risk. Patients will be compensated for their costs and will additionally receive a compensation for participating in the study.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age ≥ 18 years and ≤ 70 years
- Dutch parents and a white (Caucasian) skin tone
- No concomitant diagnose of atopic dermatitis (current), as defined by the UK Working Party Criteria
- For the case group:
 - o Vesicular endogenous hand eczema as defined by the Danish Contact Dermatitis Group and current guidelines
 - o Show both non-lesional skin and skin with visible early vesicles, but without other signs of inflammation, at time of inclusion
- For the control group (to be included after completion of the case group):
 - o 2 males and 2 females with the average age of cases

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Immunosuppressive or immunomodulatory treatment within the last 2 weeks
- UV radiation therapy within 4 weeks before biopsy
- Active bacterial, fungal or viral infection of the hands
- Other skin diseases of the hands
- Mentally incompetent: patient is unable to make important decisions regarding his or her affairs (to be determined by investigator or treating physician)
- Proven contact sensitization with clinical relevance to the hands, in which exposure to allergens is not avoided

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:	Will not start
Enrollment:	14
Type:	Anticipated

Ethics review

Approved WMO	
Date:	06-03-2018
Application type:	First submission
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	NL64339.042.17