Human skin barrier recovery

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28503

Source
Nationaal Trial Register

Brief title
HSBR

Health condition

Atopic Eczema, skin barrier, stratum corneum

Intervention

Outcome measures

Primary outcome

The lipid compostion of the stratum corneum. The lameller and lateral lipid organization.

Secondary outcome

Barrier function as Trans epidermal water loss (TEWL).

Barrier recovery monitored as TEWL over time. Here the % of barrier recovery will be calculated using the TEWL before and after disruption as 100% and 0% of barrier recovery, respectively.

Study description

Background summary

Information not provided by researcher.

Study objective

The study investigates if how the skin recovers after barrier disruption by tape-stripping and what the effects the application of a formulation is on this process. Lipophilic formulations are commonly used in the treatment of atopic eczema, yet, how these formulations exert there effect is unknown. In this study the effects of the formulation on the barrier function measured as trans epidermal water loss and the lipid composition and organization of the other most layer of the skin: the stratum corneum, are investigated. It is hypothesized that the formulation will affect the lipid composition of the stratum corneum and this changes towards a composition with better barrier properties thereby improve the skin barrier.

Study design

The trans epidermal water loss will be monitored at day 0, 1, 2, 3, 7, and 16 after barrier disruption. The lipid composition is measured by acquiring stratum corneum material at day 16 by tape stripping. Tape strips are extracted and analyzed using liquid chromatography and mass spectrometry. The lateral organization is studied at day 16 using attenuated total reflectance Fourier-transform infrared spectroscopy. The lamellar organization is studied using small angle x-ray diffraction of biopsy obtained at day 16.

Intervention

Treatment with a venix caseosa based formulation

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

- Age between 18-40

- Caucasian

Exclusion criteria

- Abundant hair presence on the ventral forearms;

- Unnatural abnormalities on one of their ventral forearms (e.g. skin lesions, tattoos);

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

- Chronically inflammatory disease;

- Dermatological disorders or a history of dermatological disorders;

- History of drug abuse;

- Pregnancy;

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Suspended

Start date (anticipated):	19-10-2015
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion
Date: 12-01-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43983
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7003
NTR-old	NTR7193
CCMO	NL51870.058.14
OMON	NL-OMON43983

Study results