Efficacy of a skin protecting cream in skin barrier protection and repair

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON38880

Source
ToetsingOnline

Brief title
Efficacy of a skin protecting cream in skin barrier protection and repair

Condition

- Epidermal and dermal conditions

Synonym
Contact dermatitis / contact eczema

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Despharma

Intervention

Keyword: Irritation response, Protective cream, Skin barrier

Outcome measures

Primary outcome

To assess the skin barrier and irritation response the following parameters

will be measured:

1. Transepidermal water loss (TEWL), pH and erythema

2. Levels of natural moisturizing factors (NMFs) (including

2-pyrrolidone-5-carboxylic acid, histidine and urocanic acid) and cytokines

(including IL-1α, IL-1β, Il-1RA, IL-8 and IL-10) in the stratum corneum

harvested by using adhesive tape

3. Skin morphology as assessed by using confocal laser scan microscopy

(Vivascope 1500, MAVIG, Germany)

4. Lipids (ceramides and free fatty acids) in the stratum corneum harvested by

using adhesive tape

Secondary outcome

not applicable

Study description

Background summary

The epidermal barrier function of the skin resides in the stratum corneum (SC). Exposure to skin irritants like soaps, organic solvents and even water can reduce the hydration status of the epidermis and cause changes in the composition and organization of the SC lipids leading to xerotic skin and

inflammation. In addition to environmental influences, some skin diseases such as atopic dermatitis are characterised by an intrinsically reduced skin barrier. The recent identification of loss-of-function mutations in the gene encoding for filaggrin protein (FLG) as a remarkably strong risk factor for AD has been a major breakthrough, revealing that between 14% and 56% of AD cases are carriers of at least one FLG mutation. Filaggrin is a key epidermal protein that regulates several functions critical for the structure and composition of the stratum corneum (SC). The well-established association between FLG mutations and AD supports the hypothesis that an intrinsically impaired skin barrier may be a primary step in the development of AD. Furthermore, we have recently shown that carriers of FLG mutations have increased risk to develop chronic irritant contact dermatitis, which is one of the most common occupational diseases. Recently, several new barrier repair creams have been put on the market aiming at restoration and protection of the skin barrier., however clinical efficacy data for these products are limited.

Study objective

The main objective of this study is to assess the in vivo efficacy of a skin protecting cream against skin irritation experimentally induced by sodium lauryl sulphate. Next, we aim to investigate whether the protective effect differs between individuals with a healthy skin barrier and individuals with an intrinsically impaired skin barrier caused by AD and/or FLG mutations.

Study design

Observational study

Study burden and risks

There are no health risks and only minor burden associated with participation in this study. The outcome of this study (assessment of the efficacy of a protective barrier cream) will contribute to prevention and improved treatment of irritation-induced skin inflammation. This will be especially useful for occupations with a high risk of contact eczema due to exposure to skin irritants (e.g. hairdressing, nursing, metalworking).

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

1) age between 18 and 55 years,
2) Caucasian race of Western Europe origin

Exclusion criteria

1) dermatitis on mid-volar arms
2) systemic inflammation disease
3) skin disease other than AD
4) use of antihistaminics or inflammation suppressing medicines (e.g. corticosteroids, NSAIDs) or antibiotics one month prior to, and during the investigation.
5) sunbathing or using a tanning bed during 2 months prior to, and during the investigation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2013
Enrollment:	170
Type:	Actual

Medical products/devices used

Generic name:	Skin barrier repair accelerator cream
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL43221.018.13