Efficacy of a skin barrier repair cream (Dermalex Eczema/ Atopifin) in atopic dermatitis patients

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The primary objective of this study is to compare the therapeutical effect on atopic dermatitis of a standard used emollient (Unguentum leniens FNA) compared to a skin barrier repair cream (Dermalex Eczema), assessed by clinical and subjective...

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

Summary

ID

NL-OMON38502

Source
ToetsingOnline

Brief title
Skin barrier repair cream in atopic dermatitis

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: OMEGA PHARMA INNOVATION AND DEVELOPMENT NV

Intervention

Keyword: Atopic Dermatitis, Protective cream, Skin barrier

Outcome measures

Primary outcome

The primary outcome parameter in this study is transepidermal water loss (TEWL)

as an effect parameter for the skin barrier function

Erythema (skin redness) for the extent of skin inflammation

Secondary outcome

Change of severity of atopic dermatitis

Skin hydration

Change in itching

The amount of used cream/ointments (per day and total)

Experiences of the subjects on different ointments and effect on skin / eczema

symptoms.

Study description

Background summary

Atopic eczema (AD) is a chronic and relapsing inflammatory skin disorder with a wide spectrum of clinical presentations and combinations of symptoms. Skin barrier dysfunction, which can be inherited or acquired, is a major hallmark of AD, allowing for enhanced allergen and microbial penetration across the skin. A defective skin barrier in AD exists even in nonlesional skin and is characterized by increased transepidermal water loss (TEWL) as well as enhanced percutaneous penetration of chemicals.
Current treatment of AD is the administration of topical corticosteroids or immunosuppressive ointments to counter the immunological reaction and to control flares. However, prolonged use of these treatments can induce side-effects on long-term, stressing the need to develop new treatment applications. Therapeutic intervention in AD should be aimed at both restoring

skin barrier function and reducing inflammation in the entire integument in general and in AD lesions in particular, as impaired skin barrier function is present in lesional as well as clinically uninvolved skin. Emollients have been shown to restore skin barrier function and their frequent and generous use is an essential part of the treatment regimen of AD. The investigated skin barrier repair cream (Dermalex Eczema) contains magnesium salt and ceramides, both known to influence skin barrier and inflammation. Clinical efficacy data for these skin barrier repair creams are limited

Study objective

The primary objective of this study is to compare the therapeutical effect on atopic dermatitis of a standard used emollient (Unguentum leniens FNA) compared to a skin barrier repair cream (Dermalex Eczema), assessed by clinical and subjective evaluation.

Study design

single-center, intra-individual comparison (right/left) intervention study

Study burden and risks

There are no health risks associated with this study.
All measurements are non-invasive with a sensor on the skin.
Patients with atopic dermatitis are used to use of daily ointments on their skin, so 4 weeks use of 2 different ointments will not be an extra burden.This study will provide information whether use of a protective skin barrier cream is usefull in treatment of atopic dermatitis. In addition, if the protective skin barrier cream is more efficient than a neutral ointment. Dermalex contains no corticosteroids avoiding side effects caused by prolonged use of local corticosteroids.

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

Clinically diagnosed atopic dermatitis
Mild to moderate atopic dermatitis
At least two symmetrical (i.e. left and right side of the body) skin sites with comparable atopic dermatitis severity
Age between 18 and 70 years

Exclusion criteria

- Other skin disease other than AD.
- Use of antihistamines prior to (72 hours) the study and/or expected use during the study.
- Use of antibiotics prior to (4 weeks) the study and/or expected use during the study.
- Use of inflammation suppressing medicines (e.g. corticosteroids, NSAIDs) prior to (4 weeks) the study and/or expected use during the study
- Use of systemic suppressing drugs (e.g. prednisone, methothrexate) prior to (4 weeks) the study and/or expected use during the study
-Severe disorders within the last 6 months before study (e.g. cancer, acute cardiac or circularity disorders, HIV, infectious hepatitis)
- Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements.

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):	20-12-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	13-11-2013
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	NL46576.018.13