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

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The primary objective of this study is to compare the therapeutic effect on atopic dermatitis of a skin barrier repair cream (Dermalex eczema) in contrast to a standard used emollient (unguentum leniens FNA) and a dermatocorticoid (hydrocortisone)…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON41112

Source
ToetsingOnline

Brief title
Efficacy of Dermalex eczema in atopic dermatitis patients

Condition

- Epidermal and dermal conditions

Synonym
atopic Dermatitis, Atopic eczema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dermalex, dermatitis, eczema, RCT

Outcome measures

Primary outcome

The duration in days of used ointments until AD symptoms have improved, defined

as a decrease in SCORAD-score of 5 points

Secondary outcome

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

- Change in cytokine levels, lipid profile, Trans epidermal water loss,

erythema and PH after the different treatments.

- presence of mutations on the Fillagrin-gene

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. It affects up to 20 percent of children and 2-10 percent of adults and often predates the development of allergic airway diseases like rhinitis and asthma. Skin barrier dysfunction, which can be inherited or acquired, is a major hallmark of AD. A defective skin barrier in AD exists even in nonlesional skin 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 the long-term, stressing the need to develop new treatment applications.
The occlusive effect of emollients are temporary and do not actively improve the skin barrier function. The investigated skin barrier repair cream (Dermalex Eczema) contains magnesium salt and ceramides, both known to stimulate the synthesis of stratum corneum lipids which are the principal barrier of the skin. The aim of this study is to investigate the efficacy of Dermalex eczema cream to a class 1 dermatocorticosteroid (hydrocortisone) en a frequently used emollient (koelzalf)

immune response.

Study objective

The primary objective of this study is to compare the therapeutic effect on atopic dermatitis of a skin barrier repair cream (Dermalex eczema) in contrast to a standard used emollient (unguentum leniens FNA) and a dermatocorticoid (hydrocortisone) assessed by clinical evaluation and biophysical parameters.

Study design

This is a multi-center, randomized, intra-individual comparison (right/left) intervention study

Intervention

Patients are instructed to apply Dermalex eczema cream, a standard emollient or a dermatocorticosetroid on one side of the body on atopic dermatitis lesions at least twice a day. The opposite side will be topically treated with another of the three creams twice a day. The patients will be randomized in three groups: Dermalex eczema versus unguentum leniens, Dermalex eczema versus hydrocortisone and unguentum leniens versus hydrocortison. Within the groups the creams will be assigned right or left in a randomized order.

Study burden and risks

Negligible risk. The possibility of a (mild) Allergic reactions to ingredient can not be ruled out but the risk is not increased compared to other over-the-counter products.

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, according to total SCORAD score (score <25) ;- Age between 18 and 70 years;- Written informed consent ;- At least two symmetrical (i.e. left and right side of the body) skin sites with comparable AD severity (Measured in SCORAD-score)

Exclusion criteria

Extensive UV exposure in the last 14 days before study and/or expected during the study. ;- Other skin disease other than AD.;- Use of antibiotics 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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Dermalex eczema
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Hydrocortisone1%
Generic name:	Hydrocortisone1%
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	24-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-07-2014
Application type:	Amendment
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
EudraCT	EUCTR2014-001179-30-NL
CCMO	NL48640.018.14