Efficacy of Dermalex Eczema in atopic dermatitis patients

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23349

Source
NTR

Brief title
EDA

Health condition

Atopic dermatitis

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: AMR

Intervention

Outcome measures

Primary outcome

Changed 22-may-2015:
1) Change in modified SCORAD in three and six weeks

Secondary outcome

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

- Change in cytokine levels, lipid profile, Trans epidermal water loss and PH after the different treatments.

- presence of mutations on the Fillagrin-gene

Study description

Background summary

NA

Study objective

Dermalex eczema cream will decrease symptoms of atopic dermatitis significantly and will be superior to Unguentum leniens and Hydrocortison when used for a 6 week period

Study design

week 0, week 3, week 6

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.

Contacts

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Eligibility criteria

Inclusion criteria

- Clinically diagnosed atopic dermatitis

- Mild to moderate atopic dermatitis, according to total SCORAD score (score <25 and <50 respectively)

- 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-05-2014
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4321
NTR-old	NTR4541
Other	METC AMC : 2014_090

Study results