Evaluation of efficacy of topical corticosteroid once daily plus emollient cream once daily vs. topical corticosteroid cream twice daily alone in chronique plaque psoriasis

No registrations found.

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

Summary

ID

NL-OMON25273

Source
NTR

Brief title
N/A

Health condition

Chronic Plaque psoriasis

Sponsors and support

Primary sponsor: Investigator Sponsored Trial
Prog Giuseppe Micali
Clinica Dermatologica
University Catania (Italy)
Source(s) of monetary or material Support: IST (Investigator sponsored trial)

Intervention

Outcome measures

Primary outcome

Facial modified Eczema Area Severity Index (EASI) using a 4-scale score (from 0 to 3) (absent, mild, moderate, severe) evaluating: erythema, infiltration, lichenification, erosion

Secondary outcome

Physician Global assessment (a 6-point scale) from 0 to 5; Tolerability will be evaluated at week 3 and at week 6 using a 4-point score (from 0: very good tolerability to 3: very poor tolerability)

Study description

Background summary

Atopic eczema (AE) is a very common skin condition in pediatric population. Skin barrier alteration and reduction of innate immune mechanisms (low production of anti-microbial peptides: AMP) are considered the hallmarks of AE. Face is frequently affected in AE representing a therapeutic challenge. A non-steroideal, anti-inflammatory moisturizing cream containing rhamnosoft, ceramides and L-isoleucine (ILE) has been recently developed for the specific treatment of AE of the face. Topical ILE has shown to stimulate a skin level the production of AMP. Niacinamide has shown to improve skin barrier. Ceramides also can reinforce the skin barrier functions in AD patients. Therefore this topical formulation has a strong rational for the use in AD subjects. In this trial we want evaluate the clinical efficacy and tolerability of a rhamnosoft, ceramides and ILE containing cream (pro-AMP cream) in the treatment of facial atopic eczema in children in comparison with a simple hydrating cream.

Study objective

To evaluate if topical corticosteroid plus emollient cream is efficacious as topical corticosteroid applied twice daily in mild to moderate plaque psoriasis

Study design

The primary outcome of the trial is the facial EASI score evaluated at baseline (time 0, after week 3, and finally at week 6). The secondary endpoints are the Physician Global assessment which will be evaluated at week 6 (end of treatment) and the Tolerability score which will be evaluated at week 3 and 6.

Both outcomes would be evaluated during the study visits (week 0, week 3 and week 6) performed in the morning and evaluated by an assessor unaware of treatment allocation.

Intervention

Investigational compound : non-steroideal, anti-inflammatory moisturizing cream containing rhamnosoft, ceramides and L-isoleucine (ILE) (Nutratopic Pro AMP)
Comparator: emollient cream containing glycerol

Both topical products will be applied twice daily on the face (1 FTU/application) for a total of 6 weeks

Contacts

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Eligibility criteria

Inclusion criteria

Men and women aged 18 years or more
Plaque psoriasis mild to moderate

Exclusion criteria

Severe plaque psoriasis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-08-2013
Enrollment:	30
Type:	Unknown

Ethics review

Positive opinion

Date:	10-07-2013
Application type:	First submission

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	NL3930

Register	ID
NTR-old	NTR4068
Other	Nutra : 01-2013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A