

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

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25273

Bron

NTR

Verkorte titel

N/A

Aandoening

Chronic Plaque psoriasis

Ondersteuning

Primaire sponsor: Investigator Sponsored Trial

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Clinica Dermatologica

University Catania (Italy)

Overige ondersteuning: IST (Investigator sponsored trial)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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-steroidal, anti-inflammatory moisturizing cream containing rhamnose, 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 rationale for the use in AD subjects. In this trial we want to evaluate the clinical efficacy and tolerability of a rhamnose, ceramides and ILE containing cream (pro-AMP cream) in the treatment of facial atopic eczema in children in comparison with a simple hydrating cream.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Investigational compound : non-steroidal, anti-inflammatory moisturizing cream containing

rharnosoft, 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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Severe plaque psoriasis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	30
Type:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	10-07-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3930
NTR-old	NTR4068
Ander register	Nutra : 01-2013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A