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Emollient creams for face and body improve eczema in children with atopic dermatitis and help to restablish the normal skin flora

Submission date
14/10/2015

Recruitment status
No longer recruiting

Registration date
16/10/2015

Overall study status
Completed

Last Edited
13/05/2021

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Eczema, also known as dermatitis, is a long-term medical condition which causes the skin to become dry, itchy and irritated. Atopic eczema (AE) is the most common type of eczema, particularly in children. It can appear anywhere on the body, but it is usually found on the face, trunk (chest and back) and around the inside of the elbows or knees. This type of eczema is called “atopic” because sufferers are more sensitive to allergens (substances which can cause an allergic reaction). The exact cause of AE is not fully understood, however it is thought that their skin does not produce as many protective oils as it should do and so the skin loses water easily. This means that the protective barrier of the skin is not as good as it should be, and so is more vulnerable to skin infections. Staphylococcus aureus is a common bacterium which lives on the skin. In people with AE, these bacteria are able to get into the skin, triggering an immune response causing “flare-ups” of symptoms. Many eczema treatments work by moisturising the skin with creams (emollients), which help to restore the skin barrier. The aim of this study is to look at the effectiveness of a new hydrating emollient cream containing a protein called isoleucine, which stimulates the skin to produce antimicrobial peptides (proteins which fight microorganisms like bacteria).

Who can participate?
Children with mild to moderate atopic eczema.

What does the study involve?
Participants are given two skin creams to apply twice a day for 8 weeks. The first cream is specially designed to be applied to the face and the second cream is specially designed for the body. At the start of the study and then after 4 and 8 weeks of using the creams, the children are examined to find out whether their eczema has improved. They are also interviewed to find out how itchy their eczema is. At the start of the study and again after 8 weeks of using the creams, the skin in the affected areas is swabbed so that the amount of Staphylococcus aureus can be measured.

What are the possible benefits and risks of participating?
Potential benefits of participating are that the creams may help to improve the symptoms of AE. There are no risks of participating in the study.

Where is the study run from?
Pediatric Clinic, University of Pavia (Italy)

When is the study starting and how long is it expected to run for?
January 2015 to September 2015

Who is funding the study?
Isdin (Italy)

Who is the main contact?
Dr Massimo Milani

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nutra-01-2015

Study information

Scientific Title
Barrier Repair Therapy in Atopic Eczema: effects of isoleucine, rhamnosoft and niacinamide facial and body creams on clinical, itch and Staphylococcus aureus skin colonization: A prospective assessor-blinbed study

Study objectives
To evaluate the clinical effects (signs of inflammation and the anti-itch effects) and Staphylococcus aureus colonization of two creams (one specifically formulated for application on face and the other formulated for the body) containing emollient, hydrating and and a Anti microbial Peptides promoting agent (Iso-leucine) in children with mid to moderate atopic eczema.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB Pavia Hospital, 18/12/2014

Study design
Prospective assessor-blinded single-arm multi-centre study

Primary study design
Interventional

Secondary study design
Single-arm prospective assessor blinded trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Atopic Eczema

Interventions
Participants are provided with two products concurrently to apply twice daily for 8 consecutive weeks:

1. Participants apply 2 Finger Tip Units (1g) of the Nutratopic pro-AMP facial cream containing rhamnosoft, niacinamede and isoleucine to the face
2. Participants apply 5 Finger Tip Units of the Nutratopic pro-AMP body cream containing rhamnosoft, niacinamede and isoleucine the the body (upper, lower arms and trunk).

At baseline, week 4 and week 8, eczema severity, scoring redness, thickness scratching and lichenification are assessed. Skin swabs are taken for detection of S. aureus were obtained from lesional skin at baseline and at month 2.

Intervention Type
Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)
1. Nutratopic pro-AMP facial cream 2. Nutratopic pro-AMP body cream

Primary outcome measure
1. Eczema severity is measured using the Eczema Severity Index score (4-point scale) at baseline, week 4 and week 8
2. Itch intensity evaluated by a 10-cm Visual Analogue Scale at baseline, week 4 and week 8

Secondary outcome measures
Staphylococcus aureus skin colonization is obtained from lesions using skin swabs at baseline and 2 months.

Overall study start date
01/01/2015

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Aged between 2 and 18 years
2. Mild to moderate atopic eczema according to Hanifin diagnostic criteria

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
45

Total final enrolment
45

Key exclusion criteria

1. Severe form of atopic eczema
2. Use of corticosteroids, calcineurin inhibitors or systemic or topical antibiotics in the 4 weeks prior to enrollement

Date of first enrolment
02/01/2015

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Italy

Study participating centre
Pediatric Clinic, University of Pavia
IRCCS Policlinico "S. Matteo" Foundation
Pavia
Italy
20125

Sponsor information

Organisation
Isdin

Sponsor details
Viale Abruzzi 3
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Isdin

Results and Publications

Publication and dissemination plan
Planned publication in an indexed international scientific journal (Pediatric Allergy and Immunology).

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/01/2016	13/05/2021	Yes	No