

# Efficacy of emollient, anti-inflammatory cream containing Isoleucine vs. standard emollient cream in children with facial atopic dermatitis

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21723

### Source

NTR

### Brief title

N/A

### Health condition

Atopic dermatitis of the face in children

## Sponsors and support

**Primary sponsor:** Investigator Sponsor Trial

Prof GL Marseglia

Pediatric Clinic Ospedale San Matteo

**Source(s) of monetary or material Support:** Investigator sponsored trial

## Intervention

## Outcome measures

### Primary outcome

1 - Efficacy of emollient, anti-inflammatory cream containing Isoleucine vs. standard ... 13-05-2025

EASI score (eczema, itch, infiltration,escoriation)

## **Secondary outcome**

Investigator global assesement

## **Study description**

### **Background summary**

The hypotesis is that a cream containing rhamnosoft, nuiacinamide and isoleucine could be more efficacious.

### **Study objective**

Isoleucine is an aminoacid showing in vitro efficacy in increasing keratinocytes to increase the production of Antimicrobial peptides (AMP)such as beta defensine. In AD there is a reduced production of AMP

### **Study design**

Evaliation of EASI score (facial) at baseline

3 weeks

6 weeks (end of treatment)

### **Intervention**

Cream containing rhamnosoft, niacinamide and Isoleucine

Standard emollient cream (glycerol)

## **Contacts**

### **Public**

Via Nota 18

Massimo Milani

Milaan

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## Scientific

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## Eligibility criteria

### Inclusion criteria

Children aged 1-12 years

Atopic Dermatitis mild to moderate

Presence of lesions on the Face

### Exclusion criteria

Severe AD

Treatment with systemic anti-inflammatory drugs

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	01-09-2013
Enrollment:	80
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	21-07-2013
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	NL3914
NTR-old	NTR4084
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A