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Clinical-instrumental evaluation of the efficacy of a cosmetic product for subjects with atopic dermatitis

Submission date
31/08/2026

Recruitment status
No longer recruiting

Registration date
23/09/2026

Overall study status
Completed

Last Edited
15/09/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Study Code_Order
H.E.HU.AD.NSO05.020.11.00_IT0000467/26

Protocol Number
PIT0000216/25_Rev.02

Study information

Scientific Title
Placebo-controlled clinical-instrumental evaluation of the efficacy of a cosmetic product for subjects with atopic dermatitis

Study objectives
To evaluate the efficacy of a cosmetic product in improving skin discomfort and clinical signs (such as dryness, desquamation, erythema, and itching) in subjects with mild to moderate atopic dermatitis

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Healthy subjects with atopic dermatitis

Interventions
The investigational product is JP_25_006, containing aqua, cetearyl alcohol, ethylhexyl laurate, glycerin, ceteareth-20, clay, citric acid, potassium sorbate.
The placebo contains aqua, cetearyl alcohol, ethylhexyl laurate, glycerin, ceteareth-20, citric acid, potassium sorbate.
Half of the recruited subjects are randomized to receive the active product, while the other half receive the placebo. The principal investigator or a designated delegate dispenses the investigational products according to the randomization list.
The study is conducted as a double-blind trial: subjects, investigators, and collaborators are blinded to product allocation. Both the active and placebo products are provided in identical packaging, with no distinguishable differences between them.
The study foresees 28 days of product use. Evaluations are performed before (T0), immediately after product application (Timm) and after 7 (T7) and 28 (T28) days of use.
The product is applied onto the affected area for 28 consecutive days.

Intervention Type
Other

Primary outcome(s)
1. Skin moisturization measured using a Corneometer®, which measures changes in capacitance related to the water content of the superficial skin layer (approximately 10–20 µm) at T0, T7, T28

2. Transepidermal water loss (TEWL) measured using Tewameter 300® (Courage+Khazaka electronic GmbH), based on the TEWAMETER® method. TEWL quantifies the rate of water loss through the skin and is expressed as g/m²/h at T0, T7, T28

3. Assessment of SCORAD clinical scoring by the dermatologist measured using the SCORAD software (version 5.0), based on the assessment of the extent and intensity of atopic dermatitis and subjective symptoms (pruritus and sleep loss) at T0, T7, T28

4. Assessment of PO-SCORAD by the subject measured using he PO-SCORAD software (version 5.0), based on the subject's assessment of the extent and intensity of atopic dermatitis and subjective symptoms (pruritus and insomnia) at T0, T7, T28

5. LC-OCT on 22 subjects measured using Line-field Confocal Optical Coherence Tomography (LC-OCT) with 3D vertical stacks and isotropic cellular resolution at T0,T28

Key secondary outcome(s)
1. Self-evaluation during application (Timm) measured using a subject-reported discomfort score during the first product application at T0

2. Self-assessment questionnaire measured using a subject-reported questionnaire evaluating the subjects' perception and opinion of the tested products at T0,T7,T28

3. Quality of life measured using a modified quality of life questionnaire completed by subjects before product use and at the end of the study at T0,T28

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Healthy female and male subjects (with no specific repartition)
2. Aged over 18 years
3. Caucasian ethnicity
4. Subjects showing clinical signs and skin discomforts typical of mild to moderate atopic dermatitis on the face and/or body, with skin characterised by dryness, desquamation, erythema and itching symptoms (mild to moderate severity; SCORAD score between 15 and 40)
5. Subjects registered with the National Health Service
6. Subjects certifying the truthfulness of the personal data disclosed to the investigator
7. Subjects able to understand the language used in the investigation centre and the information provided by the investigator
8. Subjects able to follow the investigator's instructions and comply with the study constraints and specific requirements
9. Pharmacological therapy (except for therapies specified in the non-inclusion criteria) stable for at least 1 month, with no changes expected or planned during the study
10. Willingness not to use products likely to interfere with the product being tested
11. Commitment not to change daily routine or lifestyle during the study
12. Subjects who have signed an informed consent form

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Subject not satisfying the inclusion criteria
2. Subjects with acute or chronic diseases that may interfere with the study outcomes or are considered dangerous for the subject or incompatible with the study requirements
3. Subjects participating in, or planning to participate in, other clinical trials
4. Subjects deprived of freedom by administrative or legal decision, or under guardianship
5. Subjects who cannot be contacted in case of emergency
6. Subjects planning hospitalisation during the study period
7. Subjects admitted to a health or social care facility
8. Subjects who have participated in a similar study without observing an adequate washout period

9. Subjects with an acute, chronic or progressive illness that may interfere with study data or is considered by the investigator to be hazardous for the subject or incompatible with the study requirements
10. Subjects receiving pharmacological treatment that is incompatible with the study requirements
11. Subjects with a skin disease or condition that may interfere with study data or is considered by the investigator to be hazardous for the subject or incompatible with the study requirements
12. Subjects with known allergies to cosmetic products, toiletries, medications, patches or cosmetic devices
13. Women who are breastfeeding, pregnant, or unwilling to take the necessary precautions to avoid pregnancy during the study (if of childbearing potential)

Date of first enrolment
25/02/2026

Date of final enrolment
10/04/2026

Locations

Countries of recruitment
Georgia

Italy

Romania

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Sponsor information

Organisation
OMEIA SA

Funder(s)

Funder type

Funder Name
OMEIA SA

Results and Publications

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?
Protocol file	version 2	30/12/2025	01/09/2026	No	No