ISRCTN11607227 https://doi.org/10.1186/ISRCTN11607227

How effective is Profhilo Haenkenium at ameliorating atopic dermatitis symptoms in adults?

Submission date
15/04/2020

Recruitment status
No longer recruiting

Registration date
24/04/2020

Overall study status
Completed

Last Edited
27/04/2020

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Atopic dermatitis (AD) is the most common type of eczema, a condition that causes the skin to become itchy, dry and cracked. The aim of this study is to assess the effectiveness of Profhilo Haenkenium for treating the clinical symptoms of atopic dermatitis.

Who can participate?
Patients aged 18 to 65 with mild to moderate atopic dermatitis

What does the study involve?
Participants are asked to attend clinic visits at screening and then after 7, 14 and 28 days of product use. During the first visit the dermatologist informs the participants about the study procedure, risks, and benefits. Only participants giving their informed consent will be enrolled in the study. The participants are randomly allocated use the Profhilo Haenkenium cream or a placebo (dummy) product for 28 days, applying on the area affected by atopic dermatitis twice a day or more, according to their individual needs. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 28 days with an intermediate check at 7 and 14 days.

What are the possible benefits and risks of participating?
The potential benefits are improvements of atopic dermatitis symptoms. All the ingredients included in the product are approved for their use in cosmetic products and are used at the permitted concentration. The potential risks associated with the use of the product (e.g. skin irritation, sensitization, etc) are assumed to be mild to moderate and are not expected to pose a risk to human health. Risks associated with the procedures involved in this study are judged as minor. All the measurements carried out are not invasive and no skin side effects are expected from the measurement process.

Where is the study run from?
Complife Italia Srl (Italy)

When is the study starting and how long is it expected to run for?
March 2019 to March 2020

Who is funding the study?
IBSA Farmaceutici (Italy)

Who is the main contact?
Dr Vincenzo Nobile
vincenzo.nobile@complifegroup.com

Contact information

Type(s)
Scientific

Contact name
Dr Vincenzo Nobile

ORCID ID
https://orcid.org/0000-0001-9147-302X

Contact details
Via Monsignor Angelini, 21
San Martino Siccomario
Italy
27028
+39 (0)382 25504
vincenzo.nobile@complifegroup.com

Additional identifiers

Protocol serial number
E.HU.006-0030.05.23SL_2019/VN01

Study information

Scientific Title
Placebo-controlled clinical-instrumental assessment of the efficacy of a cosmetic product adjuvant for the amelioration of atopic dermatitis symptoms

Acronym
PHDermatitis

Study objectives
What is the efficacy of the test product at ameliorating atopic dermatitis symptoms in adults?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2019, Ethics Committee for Non-Pharmacological Clinical Investigations (Comitato Etico per le Indagini Cliniche Non Farmacologiche, Via XX Settembre 30/4 – 16121 Genova, Italy; +39 (0)10 5454842; a.scudieri@studinonfarmacologici.it), ref: Rif. 2019/03

Primary study design
Interventional

Study design
Single-centre placebo-controlled trial

Study type(s)
Treatment

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

Interventions
A restricted randomisation list was created using PASS 11 (version 11.0.8; PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit edition (Microsoft, USA) by a biostatistician and stored in a safe place. Randomisation sequence was stratified using “Efron's biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence was concealed by the study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). The A4 sheet reporting the unblinded treatment was folded to render the envelope impermeable to intense light. After acceptance of the subject in the study, the appropriate numbered envelope was opened. An independent technician dispensed either active or placebo products according to the card inside the envelope. The study adhered to established procedures to maintain separation between the investigator and its collaborators and the staff that delivered the intervention. Investigator and its collaborators who obtained outcome measurements were not informed on the product group assignment. Staff who delivered the intervention did not take outcome measurements. Subjects, investigator and collaborators were kept masked to products assignment.

The control group received a placebo product. Same cream of the active product without the following ingredients: sodium hyaluronate HMW, sodium hyaluronate LMW, salvia haenkei extract.

Participants are asked to attend clinic visits at screening and then after 7, 14 and 28 days of product use. During the screening/baseline visit the dermatologist informs the participants about the study procedure, risks, and benefits. Only participants giving their informed consent will be enrolled in the study. The participants will then use the Profhilo Haenkenium cream for 28 days, as follows: “Apply on the area affected by atopic dermatitis twice a day or more, according to individual needs”. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 28 days with an intermediate check at 7 and 14 days.

Intervention Type
Other

Primary outcome(s)

1. Atopic dermatitis severity assessed using SCORAD questionnaire at baseline and after 7, 14, 28 days of treatment
2. Atopic dermatitis signs of amelioration assessed by the participants using POEM questionnaire at baseline and after 7, 14, 28 days of treatment
3. Itching sensation measured using a 0-10 visual analogical scale (VAS) at baseline, immediately after product application and after 0.5 and 1 hour from product application

Key secondary outcome(s)
1. Skin moisturization measured using Corneometer® CM 825 (Courage + Khazaka electronic GmbH) at baseline, 1 hour after product application, and after 7, 14, 28 days of treatment
2. Transepidermal water loss (TEWL) measured using Tewameter® TM 300 (Courage + Khazaka electronic GmbH) at baseline, 1 hour after product application, and after 7, 14, 28 days of treatment

Completion date
10/03/2020

Eligibility

Key inclusion criteria
1. Male or female subjects, aged 18 years or older at the screening visit
2. Caucasian ethnicity
3. Subjects with a diagnosis of AD for at least 6 months prior to Day 1 visit
4. Subjects with basal SCORAD between 25 and 40
5. Adequate rest period between two similar studies
6. Willingness to not use products likely to interfere with the product to be tested
7. Willingness to not use, during all the study period, face creams other than the products supplied
8. Subject of childbearing potential is under effective contraception (oral/not oral); not expected to be changed during the study period
9. Subject informed about the study procedures and having signed an informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Subject does not meet the inclusion criteria above
2. Pregnant or breastfeeding women
3. Subject with a history of any confounding inflammatory skin diseases or any other skin disease, e.g., psoriasis, rosacea, erythroderma or ichthyosis, that could interfere with the evaluation of AD
4. Subject with spontaneously improving or rapidly deteriorating AD
5. Subject with active allergic contact dermatitis or other non-atopic forms of dermatitis
6. Subject with acute infections
7. Use within 4 weeks prior to baseline (Day 1) of oral or intravenous corticosteroids, 8. UVA/UVB therapy, PUVA (psoralen plus ultraviolet A) therapy, tanning booths, non-prescription UV light sources, immunomodulators or immunosuppressive therapies, 9. interferon, or cytotoxic drugs
8. Use within 1 week prior to baseline (Day 1) of antihistamines, topical antibiotics, topical corticosteroids, topical calcineurin inhibitors or other topical drug products used for treating AD
9. Use within 24 hours prior to baseline (Day 1) of any topical product (e.g., sunscreens, lotions, creams) in the areas to be treated

Date of first enrolment
05/11/2019

Date of final enrolment
10/12/2019

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia Srl
Via Mons. Angelini, 21
San Martino Siccomario
Italy
27028

Sponsor information

Organisation
IBSA Farmaceutici (Italy)

ROR
https://ror.org/02cf8gj49

Funder(s)

Funder type
Industry

Funder Name
IBSA Farmaceutici Italia S.r.l.

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored in Complife servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study Sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years in Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, 4 digits, and a letter. The access to the study raw data is allowed only to the study director and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and the inferential analysis (data normality and statistical test).

IPD sharing plan summary
Available on request