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Moisturizing and anti-itching efficacy of Bioakè cream for dry skin

Submission date	Recruitment status	[_] Prospectively registered
02/11/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/11/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2023	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The presence of dry skin is a common key aspect of many chronic diseases such as topic dermatitis, and can affect different areas of the body. Dry skin might be red, rough, scaly, with the presence of fissuration and it is often strictly related to chronic itch. Even if dry skin is not a critical condition, it impacts the patient's quality of life in terms of discomfort and itching. For a quick and effective resolution of the symptoms caused by skin dryness, preventive actions must be taken using an emollient, soothing and moisturizing product. The aim of this study is to assess the effect of a cosmetic product (Bioakè cream) in improving the skin barrier function and skin hydration. The study’s findings should help to improve the well-being of patients and the condition of dry skin.

Who can participate?
Healthy female subjects aged between 18 and 60 years old with sensitive, dry, and reactive skin

What does the study involve?
Bioakè cream and placebo (dummy) cream were applied on the surface of the forearm of each participant under controlled conditions by the experimenter and another area of the forearm was left untreated and acted as control. Participants were screened and enrolled under the supervision of a board-certified dermatologist. Before the visit, the participants observed a 20 /30-minute acclimatization period in these conditions. Skin properties and soothing effects were assessed before and after a single application of Bioakè cream, in comparison to a skin area treated with a placebo formulation and to an untreated area.

What are the possible benefits and risks of participating?
Bioakè cream could facilitate skin barrier restoration and hydration and provide itch relief. There are no expected risks of participating.

Where is the study run from?
Ekuberg Pharma (Italy)

When is the study starting and how long is it expected to run for?
March 2023 to March 2023

Who is funding the study?
Ekuberg Pharma (Italy)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Improvement in skin barrier function and itch relief on dry skin: a short-term, placebo-controlled study of the efficacy of Bioakè cream

Acronym
Bioakè

Study objectives
Bioakè cream (a cosmetic product) is able to reduce transepidermal water loss, improve skin moisturization and reduce itching sensation in human volunteers.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The product under investigation is a cosmetic product manufactured according to EU Regulation 1223/2009. A valid Cosmetic Product Safety assessment has been issued for Bioakè. According to this rationale and the nature of the product, ethics approval has been considered not mandatory.

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Skin dryness and itching

Interventions
Bioakè cream and placebo were applied on the volar surface of each participant (2 mg/cm2) under controlled conditions by the experimenter and another area of the forearm was left untreated and acted as control. One area of the forearm was not treated. The subjects participating in the study were screened and enrolled under the supervision of a board-certified dermatologist from a panel of healthy subjects, in accordance with inclusion and non-inclusion criteria. The evaluations are carried out in a temperature and humidity-controlled environment (respectively T = 22 ± 2°C and RH = 50 ± 10%). Before the visit, the subject observed a 20/30-minute acclimatization period in these conditions.

Skin properties (transepidermal water loss and hydration) and soothing effects were assessed before and after a single application of Bioakè cream, in comparison to a skin area treated with a placebo formulation and to an untreated area.

Intervention Type
Other

Primary outcome(s)
1. Transepidermal water loss measured using the internationally recognized TEWAMETER® method. The used instrument is a Tewameter 300® (Courage+Khazaka, electronic GmbH) at baseline (T0) and 4 hours after the single product application.
2. Skin hydration measured using a CORNEOMETER® at baseline (T0) and 4 hours after the single product application.
3. Itching relief: after a capsaicin solution was applied to the skin of both nasolabial fold sides of each volunteer, the experimenter scores the intensity of the perceived discomfort immediately after and 1, 2, 3, 4, 5, 7, 10 minutes after the first product application. At each monitored time the experimenter registers, with the collaboration of the subject, the intensity of the perceived discomfort sensations (stinging/itching sensation), according to the scores: 1 = no reaction; 2 = mild reaction; 3 = moderate reaction; 4 = severe reaction.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Registered with the National Health Service (NHS)
3. Aged between 18 and 60 years old
4. Caucasian ethnicity
5. Subjects with sensitive, dry and reactive skin
6. Subject with positive reaction to stinging test with capsaicin (10% hydroalcoholic capsaicin 3.6 x 10-3%)
7. Subjects certifying the truthfulness of the personal data disclosed to the investigator
8. Subjects able to understand the language used in the investigation center and the information given by the investigator, as well as able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
9. The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least 1 month without any changes expected or planned during the study
10. Commitment not to change one's daily routine and lifestyle
11. Subjects aware of the test procedure and have signed an informed consent form

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
Female

Key exclusion criteria
1. Acute or chronic diseases capable of interfering with the outcome of the study or that are considered dangerous for the subject or incompatible with the requirements of the study
2. Taking part or planning to participate in other clinical trials and participated in a similar study without respecting an adequate washout period
3. Undergoing drug therapy considered by the investigator to be reactions incompatible with the requirements of the study
4. Clinical history of irritative to cosmetics, drugs, patches or cosmetic devices
5. Breastfeeding or pregnant

Date of first enrolment
20/03/2023

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Italy

Study participating centre
Complife
Via Angelini, 21
San Martino Siccomario (PV)
Italy
27028

Sponsor information

Organisation
Ekuberg Pharma

Funder(s)

Funder type
Industry

Funder Name
Ekuberg Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Complife Italia server). 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 in an electronically signed PDF file. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by means of a code generated by the

Complife volunteer’s management software. The code is composed of a letter, four digits, and a letter. Access to the study's raw data is allowed by application only to the study director and the person designated by him to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary

Stored in non-publicly available repository