

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

<b>Submission date</b> 02/11/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/11/2023	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?  
Davide Carati, [davide.carati@ekubergpharma.com](mailto:davide.carati@ekubergpharma.com)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

## 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/cm<sup>2</sup>) 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  $T = 22 \pm 2^{\circ}\text{C}$  and  $\text{RH} = 50 \pm 10\%$ ). 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<sup>-3</sup>%)
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