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How effective are natural dermocosmetics at reducing dermatitis symptoms?

Submission date
10/02/2022

Recruitment status
No longer recruiting

Registration date
11/02/2022

Overall study status
Completed

Last Edited
11/02/2022

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
Dermatitis is a general term for skin inflammation. The number of people with dermatitis in the world is growing rapidly every year, as is the desire and interest of consumers to include natural cosmetics in their daily rituals. This is especially important for reducing the symptoms of skin diseases, such as dermatitis, because not only synthetic but also natural cosmetics contain preservatives (based on water or oil) that irritate sensitive (and dermatitis) affected skin, causing the user to feel discomfort. Dermatitis affects an average of 10% of the world's population, up to 20% in the Nordic countries. Biologically active substances used in natural cosmetics are one of today's megatrends. Natural biotechnology provides a sustainable alternative to the production of chemically synthesized cosmetics, as well as the highest product quality. This study aims to assess the impact of a combination of natural dermocosmetics on dermatitis.

Who can participate?
People aged 18 years or over with dermatitis symptoms in the face and neck zone and/or diagnosed with dermatitis in the face and neck zone

What does the study involve?
Participants are asked to attend dermatologist visits at screening and then after 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 will then use a combination of natural cosmetic products - washing gel oil (Oil-to-Milk) and nourishing daily cream applied to the dermatitis/dry face/neck skin. At each visit, skin condition, sensations and visible changes are evaluated by the dermatologist. All the measurements are carried out using non-invasive procedures. The total duration of each visit is 15 minutes. The study duration is 28 days.

What are the possible benefits and risks of participating?
The product is intended to improve skin condition and reduce dermatitis symptoms. All of these effects are temporary. To the best of the researchers' knowledge, the risks associated with using the product are very low and are usually associated with individual sensitivity to one or more of the ingredients in the product formula.

Where is the study run from?
Aesthetica clinics (Latvia)

When is the study starting and how long is it expected to run for?
November 2021 to January 2022

Who is funding the study?
Labrains SIA (Latvia)

Who is the main contact?
Aleksandra Kozlova
aleksandra@labrains.eu

Contact information

Type(s)
Public

Contact name
Mrs Aleksandra Kozlova

Contact details
Maskavas Street 127
Riga
Latvia
LV-1003
+371 (0)26789954
aleksandra@labrains.eu

Additional identifiers

Protocol serial number
1.2.1.1/18/A/007

Study information

Scientific Title
Efficacy of use of combined skincare routine at the reduction of dermatitis symptoms

Acronym
Redesym

Study objectives
The system of delicate preservation and lipid regeneration system promotes balanced skin-cell interactions and reduce homeostasis disorders consequently reducing the symptoms of dermatitis and atopic skin conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Studies on cosmetic products are usually carried out without any approval from an ethics committee. In Europe, all cosmetic products are safe for human use according to the Cosmetic Regulation EC 1223/2009. The techniques employed in cosmetic testing, and in this study, are non-invasive to minimally invasive. The study is carried out according to the declaration of Helsinki to take into account the research ethics related to studies involving humans.

Primary study design
Interventional

Study design
Single-centre double-blinded randomized trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diagnosed atopic dermatitis, mild-to-moderate dermatitis symptoms in the facial and neck zones

Interventions
52 subjects showing the clinical signs of dry skin, mild-to-moderate dermatitis symptoms and/or diagnosed atopic dermatitis in the facial and neck zones are enrolled. Subjects are asked to attend dermatologist visits at baseline and after 28 days of product combination use. Only subjects giving their informed consent enrolled in the study.

The participants were asked not to use other cosmetics and other make-up on dermatitis/dry skin during the study.

The first group of participants are asked to apply the washing gel oil (Oil-to-Milk) to the dermatitis/dry face/neck skin in the morning and evening for 28 days. The product is washed off with water for not more than 1 minute. Afterwards participants are requested to apply the product nourishing daily cream for restoring and preserving the lipid layer of natural origin on dermatitis/dry face/neck skin.

The second group of participants are asked to apply the washing gel oil (Oil-to-Milk) to the dermatitis/dry face/neck skin in the morning and evening for 28 days. The product is washed off with micellar water of natural origin (without water). Afterwards participants are requested to apply the product nourishing daily cream for restoring and preserving the lipid layer of natural origin on dermatitis/dry face/neck skin.

At each visit, skin dermatological conditions and dermatitis symptoms are evaluated by the dermatologist. All the check-ups and evaluations are carried out using minimally non-invasive procedures. The total duration of each visit is 15 minutes. The study duration is 28 days.

Intervention Type
Other

Primary outcome(s)
1. Severity of skin condition in the dimension of skin sensations, measured by a Likert scale from 0 - no feeling to 5 - acute or severe in four dimensions (sting sensation/tingling; burning/heat sensation; heat wave; skin irritation/discomfort/sensitivity) at baseline and 28 days

2. Severity of skin condition in the dimension of visible skin changes, measured by a Likert scale from 0 - no symptoms to 5 - acute or severe in four dimensions (diffuse redness/flushing; extended vascular networking; rash; edema/swelling) at baseline and 28 days

Key secondary outcome(s)
Skin visual appeal and overall participant quality of life changes associated with the symptoms of dermatitis assessed during the discussion and observations of a dermatologist at baseline and 28 days

Completion date
03/01/2022

Eligibility

Key inclusion criteria
1. Patients over the age of 18 years
2. Diagnosed atopic dermatitis and/or mild-to-moderate dermatitis symptoms in the facial and neck zones
3. Has not been recently involved in any other similar study
4. Willingness to use during all the study period only the product to be tested in the facial and neck zones
5. Willingness to not vary the normal daily routine

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Pregnancy
2. Scars, open lesions and wounds at the product application site
3. Allergy to any of the components of the study drug
4. The study protocol is not followed

Date of first enrolment
05/11/2021

Date of final enrolment
28/11/2021

Locations

Countries of recruitment
Latvia

Study participating centre
Aesthetica clinics
Talivalza street 15
Riga
Latvia
LV-1006

Sponsor information

Organisation
Labrains SIA

Funder(s)

Funder type
Industry

Funder Name
Labrains SIA

Funder Name
VMKC SIA

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored in the Sponsor server. A backup copy of the raw data will be also in a 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 as an Excel file. The raw data will be stored for a minimum period of 10 years in Sponsor servers. In the raw data tables, subjects

are identified by a means of a code generated by the Sponsor coding system containing 1 digit and 7 numbers. Access to the study raw data is allowed only to the study coordinator and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error, frequency analysis) and inferential analysis (data normality and statistical test).

IPD sharing plan summary

Not expected to be made available