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How effective is Hilow Haenkenium cream in hydrating and improving skin elasticity in healthy women

Submission date	Recruitment status	[X] Prospectively registered
27/02/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/03/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2020	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Many women suffer from dry skin or loss of skin elasticity.

The study aims to assess the moisturizing and elasticizing efficacy of Profhilo Body Cream.

Who can participate?
Healthy Caucasian women aged between 30 and 65.

What does the study involve?
Participants are asked to attend clinic visits at screening and then after 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 Body Cream for 28 days as directed. At each visit, skin moisturization, skin elasticity, and skin compactness are evaluated by the dermatologist. All the measurements 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 14 days.

What are the possible benefits and risks of participating?
The product is intended to be used by subjects wishing to hydrate/moisturize and improving the elasticity of their skin. The benefits associated with the study are an improvement of skin hydration/moisturization and improvement of skin elasticity. All of these effects are temporary.

To the best of our knowledge, the risks associated with using the product are very minimal and usually associated with individual sensitivity to one or more of the ingredients in the product formula.

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 2020 to April 2020

Who is funding the study?
IBSA Farmaceutici (Italy)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
H.E.HU.MP.NEL00.030.05.00_2020/IT0000511

Study information

Scientific Title
Assessment of the moisturizing and elasticizing efficacy of Hilow Haenkenium cream in healthy women: ProMoist study

Acronym
ProMoist

Study objectives
What is the efficacy of the test product in improving skin moisturization and skin elasticity in healthy women with dry skin (or a skin tendency to be dry) and skin atony (mild to moderate loss of skin elasticity)?

Ethics approval required

Old ethics approval format

Ethics approval(s)
There is not an ethics committee that ruled that ethical approval was not necessary. Studies on cosmetic products are usually carried out without any approval of 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 that we will perform 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, open label

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild-to-moderate skin atony; Skin tendency to be dry or dry skin.

Interventions
30 female subjects showing the clinical signs of dry skin and mild-to-moderate skin atony (loss of skin elasticity) are enrolled. Subjects are asked to attend clinic visits at screening/baseline and after 14 and 28 days of product use. Only subjects giving their informed consent will be enrolled in the study.

The participants will be asked to use Profhilo Body Cream on their skin (legs, thigh, gluteus, abdomen, and arms) once a day for 28 days.

At each visit, skin moisturization, skin elasticity, and skin compactness are evaluated by the dermatologist. Skin moisturization (using a Corneometer®), skin elasticity (using a Cutometer® MPA 580) and skin strippings (sampling of the outermost layers of the stratum corneum by means of Corneofix® foils) are taken at study start and after 14 and 28 days product use. All the measurements 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 14 days.

Intervention Type
Other

Primary outcome(s)
1. Skin moisturization measured using a Corneometer® at baseline, 14 and 28 days
2. Skin elasticity measured by means of Cutometer® MPA 580 at baseline, 14 and 28 days

Key secondary outcome(s)
Skin compactness and skin tolerability assessed by visualization of skin strippings taken with Corneofix® foils at baseline, 14 and 28 days

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Healthy female subject
2. Caucasian ethnicity
3. Aged between 30 and 65 years
4. Mild to moderate skin atony
5. Skin tendency to be dry or dry skin
6. Has not been recently involved in any other similar study
7. Willingness to use during all the study period only the product to be tested
8. Willingness to not vary the normal daily routine

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Subject does not meet the inclusion criteria
2. Positive history for atopy or hypersensitive skin
3. Past history of allergy or sensitivity to cosmetics, toiletries, to solar and/or topical medications
4. Any skin condition that the principal investigator deems inappropriate for participation
5. Pregnancy or nursing women

Date of first enrolment
09/03/2020

Date of final enrolment
24/03/2020

Locations

Countries of recruitment
Italy

Study participating centre
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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