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Evaluation of the anti-ageing efficacy of Hilow Haenkenium cream in healthy women

Submission date
03/06/2019

Recruitment status
No longer recruiting

Registration date
04/06/2019

Overall study status
Completed

Last Edited
20/08/2021

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
The study aimed to assess the efficacy of Profhilo Haenkenium® in improving the skin condition of subjects showing mild-to-moderate skin ageing signs and skin redness due to cold and wind

Who can participate?
Female subjects (aged between 40 and 65 years old).

What does the study involve?
Participants will use the test product on the face for the duration of the study. Skin condition will be assessed in a clinical assessment at baseline and after14, 28, 56 and 84 days product use

What are the possible benefits and risks of participating?
Benefits associated with product use and study participation are related to an improvement of skin conditions. During the study is possible that subjects would note a decrease in skin redness and wrinkles depth.
Benefits associated with product use and study participation are related to both subjective and objective adverse events (AEs) (e.g. skin irritation, sensitization, etc.). The occurrence of AEs related to individual susceptibility to specific ingredients in the product could be related to biological phenomenon that are not avoidable and cannot be considered as AEs due to product use. Potential risks are assumed to be from 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/or minimally invasive and no skin side effects are expected from the measurement process.

Where is the study run from?
Complife Italia Srl, San Martino Siccomario, Italy

When is the study starting and how long is it expected to run for?
January 2017 for one month

Who is funding the study?
IBSA Farmaceutici Italia S.r.l., Italy

Who is the main contact?
Dr Vincenzo Nobile,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E.HU.016-0050.01.005L_2017/3939

Study information

Scientific Title
Evaluation of the anti-ageing efficacy of Hilow Haenkenium cream in healthy women

Acronym
HILOW

Study objectives
The aim of the study is to evaluate the anti-ageing efficacy of Hilow Haenkenium cream in healthy women

Ethics approval required

Old ethics approval format

Ethics approval(s)
None required

Study design
Single-centre open label

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mild-to-moderate ageing skin signs and skin redness due to cold and wind

Interventions
Participants attended clinic visits at screening, baseline and after 14, 28, 56 and 84 days product use (Profhilo Haenkenium®). During the screening visit subjects were informed on study procedures, risks and benefits. Only subjects giving their informed consent were enrolled in the study. Information on the medical history of the subjects were taken only after informed consent signature and subject's eligibility to participate in the study was checked by a board-certified dermatologist. At each visit skin elasticity, wrinkle depth and skin redness are measured using non-invasive bioengineering techniques; while skin strippings (trough the stratum corneum, superficial layer of the skin) were taken using minimally invasive adhesive foils. The total duration of each visit was 30 minutes. The total study duration was 84 days.

Intervention Type
Other

Primary outcome measure
Antiageing efficacy is measured by means of wrinkle depth and total skin antioxidant capacity using Ferric Reducing Antioxidant Power (FRAP) assay at baseline, and after 14, 28, 56 and 84 days of product use.

Secondary outcome measures
Skin redness and skin elasticity/compactness assessed using clinical assessment carried out by the dermatologist and the self-assessment carried out by the subjects participating in the study at baseline, and after 14, 28, 56 and 84 days of product use.

Overall study start date
04/12/2016

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Healthy female subject
2. Caucasian ethnicity
3. Age between 40 and 65 years old
4. Subjects showing mild to moderate ageing skin signs and skin redness due to cold and wind
5. Subjects who have not been recently involved in any other similar study
6. Willingness to use during all the study period only the product to be tested
7. Willingness to not vary the normal daily routine

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
50

Total final enrolment
50

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
09/01/2017

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia Srl
Via Monsignor Angelini, 21
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Sponsor information

Organisation
IBSA Farmaceutici Italia S.r.l.

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Sponsor type
Industry

Website
https://www.ibsa.it/

ROR
https://ror.org/02cf8gj49

Funder(s)

Funder type
Industry

Funder Name
IBSA Farmaceutici Italia S.r.l

Results and Publications

Publication and dissemination plan

Planned publication in BioMed Research International in 2019

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Pages 25-33	12/03/2020	20/08/2021	Yes	No