

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

<b>Submission date</b> 03/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The study aimed to assess the efficacy of Prophiloo 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 after 14, 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

**Contact name**  
Dr Vincenzo Nobile

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

**Study type(s)**

Other

**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 (through 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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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

San Martino Siccomario

Italy

27028

**Sponsor information**

## Organisation

IBSA Farmaceutici Italia S.r.l.

## 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

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?
<a href="#">Results article</a>	Pages 25-33	12/03/2020	20/08/2021	Yes	No