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Antiageing efficacy of a food supplement

Submission date
22/12/2022

Recruitment status
No longer recruiting

Registration date
23/01/2023

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hyaluronic acid is a natural substance found in the fluids in the eyes and joints. It acts as a cushion and lubricant in the joints and other tissues. Hyaluronic acid production in the body decreases with ageing. The aim of this study is to evaluate the efficacy of a treatment composed of a cosmetic product (face cream) and a food supplement claiming antiaging efficacy on a multi-ethnic panel of subjects.

Who can participate?
Male and female subjects (multiethnic panel) aged from 35 to 65 years old showing mild-moderate signs of skin aging

What does the study involve?
Participants are asked to attend clinic visits at screening and after 14, 28, and 56 days of food supplement intake and cosmetic product use. During the screening visit, the principal investigator informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects then fix the date for the first visit. During the first visit, the subjects will answer all the questions on the medical questionnaires given by the principal investigator. The participants are then randomly allocated to use the active food supplement, the active cosmetic or the placebo products for 56 days.
According to a previously defined randomization list subjects will be divided into four study groups:
- 20 subjects apply the placebo cosmetic product and take the active food supplement
- 20 subjects apply the active cosmetic product and take the placebo food supplement
- 20 subjects apply the active cosmetic product and take the active food supplement
- 20 subjects apply the placebo cosmetic product and take the placebo food supplement
All the measurements/assessments are carried out using non-invasive procedures. The total duration of each visit is 30 minutes. The study duration is 56 days with two intermediate checks at 14 and 28 days.

What are the possible benefits and risks of participating?
The potential benefits are an improvement of basal skin conditions (wrinkles, skin moisturization, skin brightness, skin elasticity and firmness, and skin homogeneity). The potential risks are assumed to be mild to moderate and are not expected to pose a risk to

health. Risks associated with the procedures involved in this study are judged as minor. All precautions will be taken to ensure that the risk is the lowest possible. All the measurements carried out are minimally invasive and no side effects are expected from the measurement process.

Where is the study run from?
1. Complife Italia S.R.L (Italy)
2. Nutratech srl spin-off Università della Calabria (Italy)
3. Complife Beijing Testing Technology Co., Ltd (China)

When is the study starting and how long is it expected to run for?
October 2022 to July 2023

Who is funding the study?
ROELMI HPC Srl (Italy)

Who is the main contact?
Dr Ileana De Ponti
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Protocol serial number
H.E.HU.HV.NAA00.080.10.00_IT0005078/2022

Study information

Scientific Title
Clinical study for the evaluation of the antiaging efficacy of a treatment composed of a cosmetic product and a food supplement. Controlled study vs placebo

Acronym
AntiageHyalStar

Study objectives
The study is aimed to assess the efficacy of a treatment composed by a cosmetic product (face cream) and a food supplement in improving skin conditions (antiaging efficacy) on a multi-ethnic panel of 80 subjects after 14, 28 and 56 days of their use. The aim of this study is to evaluate the antiaging efficacy of the tested treatment. In particular evaluation of skin profilometry (wrinkledness), skin moisturization, skin brightness, skin elasticity and firmness are evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2022, Comitato etico indipendente per le indagini cliniche non farmacologiche (Via XX Settembre 30/4 - 16121 Genova, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2022/07

Primary study design
Interventional

Study design
Multicenter stratified randomized double-blind placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild-to-moderate skin aging

Interventions
The active food supplement intervention (ExceptionHYAL® Star) is a biotechnological ingredient belonging to the next-generation Hyaluronans, based on a specific spectrum of molecular weights (ROELMI HPC, Via Celeste Milani, 24/26, 21040 Origgio (VA), Italy); while the placebo food supplement intervention is maltodextrin and magnesium stearate. Both the active and the placebo products are used as follows: one capsule per day intake at breakfast for 56 days.

The active cosmetic intervention (CUBE C.SK.21.127(B) HPC) contains Sodium Hyaluronate (ROELMI HPC, Via Celeste Milani, 24/26, 21040 Origgio (VA), Italy), which is not present in the placebo cosmetic intervention. Both the active and the placebo cosmetic products are applied on the face two times a day (morning and evening).

Test subjects are randomized into four groups of 20 subjects as follows: one group applies the placebo cosmetic product and takes the active food supplement, one group applies the active cosmetic product and takes the placebo food supplement, one group applies the active cosmetic product and take the active food supplement and one group apply the placebo cosmetic product and take the placebo food supplement.

A restricted randomization list is created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence was stratified

using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence was concealed from the in-site study director in sequentially numbered, opaque and sealed envelopes, reporting the unblinded treatment allocation (based on the subject entry number in the study). The A4 sheet reporting the unblinded treatment was folded to render the envelope impermeable to intense light. A masked allocation sequence was prepared for the staff delivering the intervention based on the subject entry number in the study.

Intervention Type
Mixed

Primary outcome(s)
The antiaging efficacy of the tested treatment evaluated using:
1. Skin profilometry (wrinkledness) measured using Primos 3D (GFMesstechnik GmbH) at baseline (T0), 28 days (T28), T56
2. Skin moisturization measured using a CORNEOMETER® at T0, T14, T28, T56
3. Skin brightness measured using the spectrophotometer/colorimeter CM-700D (Konica-Minolta) at T0, T14, T28, T56
4. Skin elasticity and firmness measured using the suction/elongation method and the subsequent release of the skin inside the opening of the instrument (Cutometer®MPA 580, Courage+Khazaka, electronic GmbH) at T0, T28, T56

Key secondary outcome(s)
1. Dermis+ epidermis thickness and dermis density measured using high-frequency ultrasound imaging (DUB® Skin Scanner System) at T0, T28, and T56 (on five Caucasian subjects per each group)
2. Digital pictures acquired by means of Visia®-CR (Canfield Scientific) at T0, T14, T28, T56
3. Clinical evaluations of skin wrinkledness and eye-bags carried out by the experimenter according to clinical and photographic scales reported in the Skin Aging Atlas Vol 1 – Caucasian* Type - Bazin Roland at T0, T14, T28, T56
4. Product acceptability and volunteers’ perceived efficacy assessed by self-assessment questionnaire at T14, T28, T56

Completion date
07/07/2023

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Aged 35 to 65 years old (inclusive)
3. Subject showing mild-moderate signs of skin aging (mild-moderate skin roughness, dull skin, presence of uneven skin complexion)
4. 10 subjects in each group showing visible eyebags
5. In each group 5 Caucasian subjects, 5 South-American/African subjects and 10 Asian subjects
6. Subjects who have not been involved in any other similar in the last 3 months
7. Subjects registered with Nation Health Service (NHS)
8. Subjects certifying the truthfulness of the personal data disclosed to the investigator
9. Subjects able to understand the language used in the investigation center and the information given by the investigator
10. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements

11. The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least one month without any changes expected or planned during the study
12. Commitment not to change the daily routine or the lifestyle
13. Subjects who have not been recently involved in any other similar study
14. Subjects having signed their written Informed Consent form (ICF) for their participation in the study and a photograph authorization

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Subject does not meet the inclusion criteria
2. Subjects with acute or chronic diseases able to interfere with the outcome of the study or that are considered dangerous for the subject or incompatible with the study requirements
3. Subjects participating or planning to participate in other clinical trials
4. Subjects deprived of freedom by administrative or legal decision or under guardianship
5. Subjects not able to be contacted in case of emergency
6. Subjects admitted to a health or social facility
7. Subjects planning a hospitalisation during the study
8. Subjects who participated in a similar study without respecting an adequate washout period
9. Subjects having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
10. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator
11. Subjects having a skin disease or condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
12. Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices
13. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)

Date of first enrolment
27/12/2022

Date of final enrolment
12/05/2023

Locations

Countries of recruitment
China

Italy

Study participating centre
Complife Italia S.R.L
Corso San Maurizio, 25
Biella
Italy
13900

Study participating centre
Nutratech srl spin-off Università della Calabria
Via P. Bucci snc
Rende
Italy
87036

Study participating centre
Complife Beijing Testing Technology Co., Ltd
Beizhan North Street N.17, Room 902- Xicheng District
Beijing
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100089

Sponsor information

Organisation
ROELMI HPC

Funder(s)

Funder type
Industry

Funder Name
ROELMI HPC

Results and Publications

Individual participant data (IPD) sharing plan

Raw data will be stored on 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 on 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, four digits, and a letter. Access to the study raw data is allowed 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	03/01/2023	09/01/2023	No	No