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Antiageing and anti-cellulite efficacy of a food supplement

Submission date
01/02/2023

Recruitment status
No longer recruiting

Registration date
16/03/2023

Overall study status
Completed

Last Edited
18/12/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
SelectSIEVE®Rainbow is a synergy of natural compounds acting together. The functional properties of its components are safe and well known: cellulite and weight management, reduction of orange peel appearance, improvement of microcirculation.
The aim of this study is to evaluate the efficacy of a food supplement in improving face skin conditions and in reducing cellulite-derived skin imperfections

Who can participate?
Female subjects aged from 35 to 65 years old showing showing fine lines/light wrinkles, dull skin and uneven skin tone and mild to moderate cellulite-derived skin imperfections

What does the study involve?
Participants are asked to attend clinic visits at screening and after 28, and 56 days of food supplement intake. 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 take the active food supplement or the placebo products for 56 days.
According to a previously defined randomization list subjects will be divided into two study groups:
- 30 subjects take the active food supplement
- 30 subjects 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 one intermediate check at 28 days.

What are the possible benefits and risks of participating?
The potential benefits are related to an improvement of face skin parameters (skin profilometry – wrinkledness and eyebags volume), skin moisturization, skin brightness, skin evenness, skin pinkish, eyebags and dark circles appearance and of cellulite derived skin imperfections (skin smoothness, body circumferences, skin microcirculation, “orange peel” skin appearance). 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?
Complife Italia S.R.L (Italy)

When is the study starting and how long is it expected to run for?
January 2023 to April 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
Dr Ileana De Ponti

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
H.E.HU.HV.NAC00.060.09.00_IT0005576/22

Study information

Scientific Title
Placebo-controlled assessment of the efficacy of a food supplement in improving face skin conditions and cellulite derived skin imperfections

Acronym
RainbowFS

Study objectives
The study aims to assess the efficacy of a food supplement in improving facial skin conditions and in reducing cellulite-derived skin imperfections on a panel of 60 subjects after 28 and 56 days of intake. The aim of this study is to evaluate its efficacy in improving facial skin conditions and in reducing cellulite-derived skin imperfections. In particular, evaluation of face skin profilometry – wrinkledness and eyebags volume, skin moisturization, skin brightness, skin evenness, skin pinkish, eye bags and dark circles appearance, skin homogeneity and cellulite derived skin imperfections (skin smoothness, body circumferences, skin microcirculation, “orange peel” skin appearance) are evaluated

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2022, 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: 2022/09

Study design
Multicentric randomized parallel group placebo-controlled clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fine lines/light wrinkles, dull skin and uneven skin tone and mild to moderate cellulite-derived skin imperfections

Interventions
The active food supplement intervention (SelectSIEVE®Rainbow) is a synergy of natural compounds acting together in order to reduce both cellulite and body weight (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 with a glass of still water for 56 days.

Test subjects are randomized into two groups of 30 subjects as follows: one group takes the active food supplement and one group takes the placebo food supplement.
In order to standardize the volunteer’s cosmetic habits, a base face and body cream without any cosmetic activity is provided to the subjects to be used during the whole study period instead of the usual face and body care routine.

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)
1. Evaluation of face skin profilometry (wrinkledness and eyebags volume) and thighs skin profilometry (smoothness), measured using Primos 3D (GFMesstechnik GmbH) at T0, T28, T56 (days).
2. Evaluation of cellulite-induced alteration of skin microcirculation by means of a thermal camera (FLIR infrared camera – FLIR Systems AB) at T0, T28, T56.

Key secondary outcome(s))
1. Epidermis moisturization (500µm) by means of the MoistureMeterEpiD at T0, T28, T56 (days).
2. Skin brightness by means of a spectrophotometer/colorimeter CM-700D (Konica Minolta, Milan, Italy) at T0, T28, T56.
3. Dark circle color by means of a spectrophotometer/colorimeter CM-700D (Konica Minolta, Milan, Italy) at T0, T28, T56.
4. Face digital pictures acquired by means of Visioface device (Courage+Khazaka) and cellulite affected zones pictures taken using a reflex digital camera at T0, T28, T56.
5. Body circumferences measurement at level of: thigh, waistline and hips at T0, T28, T56.
6. Clinical evaluations of face skin evenness, pinkish, eyebags and dark circles appearance and of “Orange peel” skin appearance (thighs) carried out by the experimenter according to clinical and photographic scales at T0, T28, T56.
7. Product acceptability and volunteers’ perceived efficacy assessed by self-assessment questionnaire at T28 and T56.

Completion date
10/04/2023

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Age between 35 and 65 (extremes included) years old
3. Phototype I to IV included, according to Fitzpatrick classification
4. Subjects showing fine lines/light wrinkles, dull skin and uneven skin tone
5. Subjects showing mild to moderate cellulite-derived skin imperfections
6. 10 subjects per group showing visible dark circles
7. 10 subjects per group showing visible eyebags
8. Subjects who have not been involved in any other similar in the last 3 months
9. Subjects registered with Nation Health Service (NHS),

10. Subjects certifying the truthfulness of the personal data disclosed to the investigator
11. Subjects able to understand the language used in the investigation center and the information given by the investigator
12. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
13. 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
14. Commitment not to change the daily routine or the lifestyle
15. Subjects who have not been recently involved in any other similar study
16. 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
Female

Total final enrolment
66

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 hospitalization 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
30/01/2023

Date of final enrolment
10/02/2023

Locations

Countries of recruitment
Italy

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

Study participating centre
Complife Italia S.R.L
Via Fratelli Signorelli, 159
Garbagnate Milanese
Italy
20024

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).

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Stored in non-publicly available repository, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/12/2023	18/12/2023	Yes	No
Participant information sheet	in Italian version 1	01/12/2022	14/03/2023	No	Yes
Protocol file	version 1	30/01/2023	14/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes