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Evaluation of the anti-aging properties of a food supplement containing natural extracts

Submission date
29/01/2025

Recruitment status
No longer recruiting

Registration date
31/01/2025

Overall study status
Completed

Last Edited
30/01/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
Skin aging is influenced by environmental, genetic, and behavioral factors, and supporting the extracellular matrix (ECM) is key to addressing it. Environmental factors such as UV damage and reactive oxygen species (ROS) accelerate aging.
This study evaluates the effects of Dermaval™ (a blend of natural extracts) based food supplements on skin elasticity, roughness, and barrier function over 56 days. Dermaval™ aims to enhance the skin barrier, improve elasticity, reduce collagen degradation and oxidative stress.
A randomized, double-blind, placebo (dummy) -controlled trial with 64 healthy female participants will assess the efficacy of three formulations, containing three different concentrations of the active ingredients, compared to placebo. Participants will take the supplement daily, with evaluations at baseline, 28, and 56 days, alongside self-evaluations and adverse event monitoring.

Who can participate?
Healthy female women aged between 35 and 45 years

What does the study involve?
Participants will be asked to attend clinic visits at screening, at baseline and after 28 and 56 days of treatment.
During the screening visit, the medical doctor will inform the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent will be enrolled in the study.
All the measurements/assessments performed during the visits will be carried out using minimally invasive procedures.

What are the possible benefits and risks of participating?
Risks associated with the product intake are considered from low to very low, in absence of allergy/intolerances to product ingredients; other ingredients in the product formula are commonly used in dietary supplements.
The potential benefits associated with the use of the product are related to an enhancement of skin barrier function (and therefore an improvement of moisture retention, and protection against environmental stressors); an increase in skin elasticity and a reduction in roughness

(smoother and more resilient skin); a prevention of collagen and connective tissue degradation (maintenance of extracellular matrix integrity); an improvement of oxidative balance and a reduction of ROS damage (antioxidant effect).

Where is the study run from?
Nutratech S.r.l. (Italy)

When is the study starting and how long is it expected to run for?
July 2024 to March 2025

Who is funding the study?
VDF FutureCeuticals INC (USA)

Who is the main contact?
Roberta Villa, roberta.villa@complifegroup.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr Roberta Villa

Contact details
Viale Indipendenza, 11
Pavia (PV)
Italy
27100
+39 38225504
roberta.villa@complifegroup.com

Type(s)
Principal investigator

Contact name
Dr Luigi Gardi

Contact details
Via Francesco Todaro 20/22
Rende
Italy
87036
+39 984 173 5511
info@complifegroup.com

Additional identifiers

Protocol serial number
H.E.HU.HV.NMS00.060.03.00_ NT0001052/24

Study information

Scientific Title
Preliminary assessment of the anti-aging efficacy of a food supplement (three formulations with different active ingredient concentrations): a randomized, double-blind, placebo-controlled study

Acronym
SUPPLEAGE3F

Study objectives
There will be positive anti-aging effects of a food supplement in adult subjects

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/08/2024, Comitato etico indipendente per le indagini cliniche non farmacologiche (Independent Ethics Committee for Non-Pharmacological Clinical Investigations) (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2024/10

Primary study design
Interventional

Study design
Preliminary study double blind randomized parallel-group placebo-controlled

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Mild to moderate wrinkles/fine lines in crow’s feet area and uneven skin tone (ageing /photoageing spots/redness/acne scars...)

Interventions
Three variants of a food supplement containing three different concentrations of the active ingredients (Dermaval™) will be studied.
A quarter of the recruited subjects will take the first formulation of the active product, a quarter of the subjects will take the second formulation, a quarter of the subjects will take the third formulation and a quarter of the subjects will take the placebo product.
A restricted randomization list will be generated by the study director using PASS 11 software (PASS, LLC. Kaysville, UT, USA) and the appropriate randomization algorithm ("Wey's urn") and stored in a safe place.
An independent technician dispenses the products according to the randomization list.
The study will be double blind: subjects, investigator and collaborators are kept masked to products assignment.
Products will be supplied in the same packaging without any obvious differences among products.
Subjects will take the assigned food supplement (once a day) for 56 days.

Intervention Type
Supplement

Primary outcome(s)
Measured at baseline and after 28 days and 56 days of treatment:
1. Skin elasticity (R2) (Ua/Uf)
2. Skin firmness (R0) (Uf; mm)
3. Trans Epidermal Water Loss (TEWL) (g/h/m2)
4. Skin smoothness (Ra) (µm)
5. Skin roughness (Rz) (µm)

Key secondary outcome(s)
1. Lipidomic analysis on skin stripping: baseline, and after 28 days and 56 days of treatment
2. Proteomic analysis on blood sample: baseline, and after 28 days and 56 days of treatment
3. Metabolomic analysis on blood sample: baseline, and after 28 days and 56 days of treatment (specifically after 28 days+1 and after 56 days+1, i.e., the following morning after 28 and 56 days)
4. Self-evaluation questionnaire: after 56 days
5. Incidence and nature of Adverse Event (AE) and Serious Adverse Event (SAE): after 28 days and 56 days of treatment

Completion date
28/03/2025

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Caucasian ethnicity
3. Aged between 35 and 45 years (extreme included)
4. Subjects with BMI between 23.5 and 30 kg/m²
5. Subjects with fasted glucose between 100 and 120 mg/dl (assessed using a portable blood glucose meter)
6. Subjects showing clinical signs of skin ageing: mild to moderate wrinkles/fine lines in crow’s feet area and uneven skin tone (ageing/photoageing spots/redness/acne scars...)
7. Subjects registered with National 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. Commitment not to change the daily routine or the lifestyle
12. Stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
13. Subjects undergoing mechanical contraception
14. Subjects informed about the test procedures who have signed a consent form and privacy policy

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
35 Years

Upper age limit
45 Years

Sex
Female

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator (pharmacological treatments known to interfere with the tested product or having effect on metabolism)
3. Subjects with any acute, chronic, or progressive disease or skin condition that may interfere with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study*
4. Subjects participating or planning to participate in other clinical trials
5. Subjects who participated in a similar study without respecting an adequate washout period (at least month)
6. Subjects that have food intolerances or food allergies or allergy to ingredients of the study product
7. Subjects who are currently using food supplement(s) and/or topical products with the same activity as the study product, or who haven't observed an adequate washout period since stopping use (at least month)
8. Subjects admitted to a health or social facility
9. Subjects planning a hospitalization during the study
10. Subjects not able to be contacted in case of emergency
11. Subjects deprived of freedom by administrative or legal decision or under guardianship
12. Subjects with a history of drug, alcohol and other substance abuse
13. Alimentary/Eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
14. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study
15. Subjects using or recently withdrawn (less than 30 days) from any hormone-based contraception therapy

*Subjects who have unstable medical diseases (cardiac arrhythmias or ischemia, uncontrolled hypertension and hypotension, diabetes mellitus, kidney failure); subjects with a history of paralysis or cerebral vascular accident; subjects with active cancers or on chemotherapy

Date of first enrolment
28/10/2024

Date of final enrolment
10/02/2025

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech S.r.l.
Via Francesco Todaro 20/22
Rende
Italy
87036

Sponsor information

Organisation
VDF FutureCeuticals INC

Funder(s)

Funder type
Industry

Funder Name
VDF FutureCeuticals INC

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored on the Complife Italia server. 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's raw data is allowed by application 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 and inferential analysis.

IPD sharing plan summary
Stored in non-publicly available repository