ISRCTN10686369 https://doi.org/10.1186/ISRCTN10686369

Effectiveness of a food supplement on skin, hair and nail condition

Submission date
24/08/2023

Recruitment status
No longer recruiting

Registration date
25/08/2023

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
BCF Life Sciences (the sponsor of the study) is interested in assessing and comparing the effectiveness of a food supplement (at two different doses) containing Kera-Diet® at improving skin, hair and nail condition, compared with a placebo formulation and a benchmark formulation already on the market.

Who can participate?
Healthy women aged between 35 and 65 years, clinically showing visible face roughness, mild /moderate skin slackness, brittle/damaged hair and brittle nails

What does the study involve?
Participants are asked to attend clinic visits at screening and after 45 and 90 days of food supplement intake. They are randomly allocated to use the active food supplement (one of the two different doses), the benchmark or the placebo product for 90 days. There are four study groups:
1. The active study product with standard concentration (250 mg Kera-Diet®)
2. The active study product with a lower concentration (125 mg Kera-Diet®)
3. A reference product already on the market – benchmark
4. The placebo formulation
All the measurements/assessments are carried out using non-invasive procedures. The total duration of each visit is 30 minutes. The study duration is 90 days with one intermediate check at 45 days.

What are the possible benefits and risks of participating?
The potential benefits are an improvement of basal skin conditions (wrinkles, skin moisturization, skin/hair/nail brightness, skin elasticity and firmness skin density and nail hardness.
All the ingredients in the product formula are approved for their use in food/food supplements and are safe for use. Potential risks (e.g. bloating, diarrhea, stomach ache) are assumed to be from mild to moderate and are not expected to pose a risk to human health. Risks associated with the product intake/application are considered from low to very low, in the absence of allergy/intolerances to product ingredients; other ingredients in the product formula are

commonly used in dietary supplements.
All the measurements carried out are not invasive and no skin side effects are expected from the measurement process. The potential benefits due to product use are related to an improvement of skin, hair and nail condition.

Where is the study run from?
BCF Life Sciences (France)

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

Who is funding the study?
BCF Life Sciences (France)

Who is the main contact?
Dr Ileana De Ponti, ileana.deponti@complifegroup.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Ileana De Ponti

ORCID ID
https://orcid.org/0000-0003-0579-7904

Contact details
Via Guido Rossa, 1
Garbagnate Milanese
Italy
20024
+39 (0)3316841438
ileana.deponti@complifegroup.com

Additional identifiers

Protocol serial number
H.E.HU.HV.NAA00.120.10.00_IT0003409/22

Study information

Scientific Title
Comparative assessment of the efficacy of a food supplement on skin, hair and nail condition: a randomized placebo/benchmark controlled study

Acronym
KeraHair

Study objectives
The study is aimed to assess the efficacy of a food supplement (in two different doses) in improving skin, hair and nails. Additionally the study will be used for the approval of the ingredient as an individually registering ingredient by the Korea Food and Drug Administration.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/08/2022, Independent ethics committee for non-pharmacological clinical investigations (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2022/04

Primary study design
Interventional

Study design
Multicentric randomized double-blind placebo and benchmark controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Visible face roughness and mild to moderate skin slackness, brittle nails and damaged/brittle hair

Interventions
The active food supplement intervention (Kera-Diet®) is a food-grade hydrolysate of natural keratin that improves hair and nail condition: brightness, volume, density, growth and vitality. It boosts keratinocytes' endogenous glutathione production. It has a traced origin, from a sustainable protein source and it has a stable and unique profile of 17 amino acids, 83.3% in free form. It has a very high assimilation due to a very low molecular weight (100% < 800 Daltons). The Benchmark food supplement intervention is a cosmeceutical ingredient comprised of solubilized keratin, already present in the market, while the placebo food supplement intervention is maltodextrin and magnesium stearate.
All the active, benchmark and the placebo products are used as follows: four capsules per day; two capsules in the morning and two capsules in the evening for 90 days.

All participants will apply for all the study length a base cream with no cosmetic claim for face care, two times a day (morning and evening).

Participants are randomly into four groups of 33 subjects as follows:
1. 30 subjects (33 included) take the active study product with standard concentration (250 mg)
2. 30 subjects (33 included) take the active study product with a lower concentration (125 mg)
3. 30 subjects (33 included) take a reference product already on the market – benchmark
4. 30 subjects (33 included) take the placebo formulation

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. Skin profilometry (Ra parameter, wrinkle depth, wrinkle length and wrinkle area) measured in the “crow’s feet” area) using Primos 3D (GFMesstechnik GmbH) at baseline (T0), 45 days (T45), T90 days (T90)
2. Deep skin moisturization measured using a MoistureMeterEpiD at baseline (T0), 45 days (T45), T90 days (T90)
3. Skin brightness measured using the spectrophotometer/colorimeter CM-700D (Konica-Minolta) at baseline (T0), 45 days (T45), T90 days (T90)
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 baseline (T0), 45 days (T45), T90 days (T90)
5. Digital pictures acquired by means Visioface (Courage+Khazaka) at baseline (T0), 45 days (T45), T90 days (T90)
6. Skin thickness (epidermis) and fibres analysis (skin density and overall anisotropy score) measured using DeepLive™ (DAMAE Medical) at baseline (T0) and T90 days (T90)

Key secondary outcome(s)
1. Nails and hair brightness measured using the spectrophotometer/colorimeter CM-700D (Konica-Minolta) at baseline (T0), 45 days (T45), T90 days (T90)
2. Clinical evaluation of nail hardness/brightness using VAS score scales at baseline (T0), 45 days (T45), T90 days (T90)
3. Product acceptability and volunteers’ perceived efficacy assessed with a self-assessment questionnaire at T90

Completion date
19/05/2023

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Aged between 35 and 65 years old (50% of participants aged between 35 and 50 years old and 50% of the participants aged between 51 and 65 years old in each study group)
3. Damaged/brittle hair (at least 20% of subjects due to discoloration in each study group)
4. Brittle nails (not related to pathological alterations to the nail plate)
5. Clinically showing visible face roughness (crow’s feet wrinkles)
6. Mild to moderate skin slackness
7. Phototype I to IV (according to Fitzpatrick classification)
8. Registered with health social security or health social insurance
9. Signed their written Informed Consent form (ICF) for their participation in the study and a photograph authorization
10. Able to understand the language used in the investigation center and the information given
11. Able to comply with the protocol and follow protocol constraints and specific requirements

12. Willing to use the same shampoo during the whole study period
13. Willing to attend the study visit and have hair dyes performed at least 3 weeks before
14. Willing to not use during the study period products other than the test product
15. Using effective contraception (oral/not oral) if women of childbearing potential and not expected to change during the trial
16. Have not had sun exposure (both natural or artificial) for at least 2 months
17. Accept not to be exposed in an intensive way to UV rays during the whole study duration
18. Willing to not use similar products that could interfere with the product to be tested

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
132

Key exclusion criteria
1. Does not meet the inclusion criteria
2. Taking part or planning to participate in another clinical study in the same or in another investigation center
3. Deprived of freedom by administrative or legal decision or under guardianship
4. Admitted in sanitary or social facilities
5. Planning a hospitalization during the study
6. Consumption of food supplement(s) for skin/hair/nail care currently or within the past 12 weeks before the study
7. Breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential)
8. Has started or changed estrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
9. Acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator to be hazardous or incompatible with the study requirements
10. Chronic skin disease or skin-related treatment and drug intake
11. In the course of a long treatment or intending to have one considered by the Investigator liable to interfere with the study data or incompatible with the study requirements
12. Personal history of cosmetic, drug, domestic products or food supplement allergy
13. Pathological nail conditions
14. Systemic or local treatments/medications affecting nail growth

15. Radiotherapy, chemotherapy at any time
16. Skin/scalp condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
17. Systemic treatment affecting the hair growth taken for more than 4 consecutive weeks during the last 24 weeks before the inclusion visit
18. Any topical treatment applied on the scalp/skin within the last 2 weeks before the inclusion visit
19. Any following hair care within the last 2 weeks before the inclusion visit: dandruff shampoo, antifungal shampoo, dyeing, bleaching, perm
20. Any skin care-make-up/hair care product applied on the skin in the 3 hours before the visit and on the scalp between the last shampoo and the inclusion visit (e.g. gel, hairspray, wax, foam)
21. Known or suspected sensitization to one or more test formulation ingredients
22. Any condition that the principal investigator deems inappropriate for participation
23. Pharmacological treatments (topic or systemic) known to interfere with skin metabolism /physiology
24. Adult protected by the law (under guardianship, or hospitalized in a public or private institution, for a reason other than the research, or incarcerated)
25. Unable to communicate or cooperate with the Investigator due to language problems, poor mental development, or impaired cerebral function

Date of first enrolment
20/10/2022

Date of final enrolment
20/01/2023

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 Monsignor Angelini, 21
San Martino Siccomario
Italy
27028

Study participating centre
Complife Italia S.R.L
via Signorelli
Garbagnate Milanese
Italy
20024

Sponsor information

Organisation
BCF Life Sciences

Funder(s)

Funder type
Industry

Funder Name
BCF Life Sciences

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 also be included in the study report and shared with the study sponsor in an electronically signed PDF file. 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 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 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?
Results article		04/10/2024	01/09/2025	Yes	No