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Evaluation of the efficacy of an oral administration of new hyaluronan in improving skin aging signs in healthy adult women

Submission date
28/10/2020

Recruitment status
No longer recruiting

Registration date
02/11/2020

Overall study status
Completed

Last Edited
15/03/2022

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
Skin is the largest organ of the human body and represents the main barrier to the external environment. Like all other organs, it undergoes aging due to several factors. Skin ageing factors include, above all, genetic susceptibility, followed by skin pigmentation (protective against photo-ageing) and hormonal lifetime variations. External factors include exposure to UV light is the skin most affective ageing factor, accounting for more than 90% of visible skin ageing and is linked to dryness, roughness, pigmented spots, and decreased skin barrier function. In addition, another factor is smoking, which decreases blood flow to the skin, leading to oxygen and nutrient deficiency. Finally, skin ageing is influenced by other lifestyle-related factors, such as temperature, pollution, diet and physical activity, chronic stress and corticosteroid hormones release. Acting simultaneously, all these factors lead to changes to the structure and function of the skin, resulting in skin ageing signs, such as the appearance of wrinkles, furrows and changes in colour.

Years of research around skin aging has provided evidence for treatments effective in preventing and/or treating wrinkles. Considering the variety of its positive effects, hyaluronic acid (HA) is one of the most studied. The quantity of naturally occurring HA in the skin gradually decreases through aging and supplementation of HA may reduce the visible effects of skin aging. It has also been reported that oral ingestion of HA could improve dry skin.

This study aims to test the skin anti-ageing effect of an innovative HA-based food supplement: a Full Spectrum-Hyaluronan (FS-HA).

Who can participate?
Healthy adult female volunteers, 35 to 70 years old, with mild to moderate signs of skin ageing

What does the study involve?
Participants will be randomly allocated to take one capsule a day of the food supplement or the

placebo with a glass of water, away from meals, for 28 days. Skin parameters will be analyzed at enrollment and at the end of the study. HA serum level will be assessed in blood samples collected at enrolment and weekly during the study.

What are the possible benefits and risks of participating?
Benefits associated with products use are amelioration of skin ageing signs.

Risks associated with the intake of the product are considered from low to very low, in absence of allergy/intolerances to product ingredients; other ingredients in the formula of the product are commonly used in dietary supplements. All the instrumental measurements carried out are not invasive and no skin side effects are expected from the measurement process.

Blood samplings will be carried out in a Medical Analysis Laboratory by professional personnel.

Where is the study run from?
Complife Italia Srl (Italy)

When is the study starting and how long is it expected to run for?
From July 2020 to November 2020

Who is funding the study
Complife italia Srl (Italy)

Who is the main contact
Dr. Francesco Tursi
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
H.E.HU.MP.NAA00.060.14.00_IT0002127/20

Study information

Scientific Title
Oral intake of new full spectrum hyaluronan improves skin profilometry and aging factors: a randomized, double-blind, placebo-controlled clinical trial

Acronym
FS-HA STAR

Study objectives
The administration of a wide spectrum of hyaluronans ameliorates aging-related clinical signs of the skin

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/09/2020, Independent Ethical Committee for Non-Pharmacological Clinical Study Trials (Via XX Settembre 30/4, 16121 Genova, Italy; +39 (0)10 5454842; a. scudieri@studinonfarmacologici.it); ref: 2020/11

Study design
Double blind, single-centre, randomized, placebo-controlled parallel-group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See addition files for information sheet in Italian

Health condition(s) or problem(s) studied

Amelioration of the skin aging signs

Interventions
Participants will be enrolled following a dermatological visit, then assigned to one of the two groups of the study in a 1:1 ratio according to a restricted randomization list generated by using an appropriate statistic algorithm (Wey's urn). One group will receive the food supplement (200 mg hyaluronan) and the other group will receive a placebo, both groups will take one capsule /day with a glass of water, away from meals, for 28 days. Additionally throughout the study, participants will use a cosmetic cream supplied by the lab twice a day in substitution of usual skincare products.

At the end of the treatment, volunteers will return to the study facility for the dermatological assessment and an interview about the tolerance and efficacy of the treatment.

An explorative study for evaluating the plasma hyaluronic acid levels following the treatments will also be carried out on 20 subjects, with 10 participants randomly chosen from each of the study groups.

Intervention Type
Supplement

Primary outcome measure
1. Determination of the Skin moisturization evaluated as skin moisturization index using a Corneometer® and trans epidermal water loss using a TEWAMETER® probe at baseline and 4 weeks
2. Determination of skin elasticity and firmness, based on the suction/elongation method and the subsequent release of skin using Cutometer® at baseline and 4 weeks
3. Determination of skin profilometry measuring wrinkle depth and wrinkle volume using Primos 3D at baseline and 4 weeks
4. Acquisition of face digital pictures using a reflex digital camera at baseline, 1, 2, 3, and 4 weeks
5. Evaluation of serum hyaluronic acid level in a subgroup of participants at baseline, 1, 2, 3, and 4 weeks

Secondary outcome measures
1. Products tolerability, efficacy, and acceptability evaluated using a self-assessment questionnaire at 4 weeks

Overall study start date
01/07/2020

Completion date
04/11/2020

Eligibility

Key inclusion criteria
1. Healthy female subjects, showing mild to moderate signs of skin aging
2. Aged between 35 and 70 years old
3. Caucasian ethnicity
4. Observed an adequate wash-out period from similar studies
5. Give informed consent

6. Agree not to make any changes to their normal everyday routine
7. Agree not to use products with comparable activity to the study product
8. Agree not to expose in an intensive way to UV rays during the whole study duration
9. Available to take food supplements and comply with the study protocol
10. Agree to adopt an adequate contraceptive system

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Eating disorders (such as bulimia and anorexia)
2. Pregnant, breastfeeding or have planned a pregnancy during the study period
3. Previous history of gastrointestinal pathological conditions
5. Systemic pharmacological treatment
6. Under local pharmacological treatment on the skin area monitored during the test
7. Congenital or acquired immunodeficiency
8. Under treatment with food supplements which could interfere with the functionality of the product being study
9. Other skin alterations on the monitored area
10. Exposed in intensive way to UV rays during the 4 weeks prior to the study start
11. Considered as not suitable to participate in the study by the investigator
12. Reported food intolerance to one or more ingredients contained in the food supplement
13. Alcohol addiction
14. Drug addiction

Date of first enrolment
23/09/2020

Date of final enrolment
28/09/2020

Locations

Countries of recruitment
Italy

Study participating centre

Complife Italia Srl
Via Mons. Angelini 21
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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Complife Italia Srl

Results and Publications

Publication and dissemination plan
A paper will be published in relevant international peer-reviewed journals, such as the European Journal of Dermatology.

Intention to publish date

15/11/2020

Individual participant data (IPD) sharing plan

Raw data will be stored in 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 in 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, 4 digits, and a letter. The access to the study raw data is allowed only to the study director and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and the inferential analysis (data normality and statistical test).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v0	06/07/2020	06/11/2020	No	Yes
Results article		01/12/2021	15/03/2022	Yes	No