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A food supplement and cosmetic product treatment based on a new hyaluronic acid for anti-aging effects on the skin of adult females

Submission date
23/12/2020

Recruitment status
No longer recruiting

Registration date
30/12/2020

Overall study status
Completed

Last Edited
24/08/2022

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
Hyaluronic acid, also known as hyaluronan, is a clear, gooey substance that is naturally produced by your body. The largest amounts of it are found in your skin, connective tissue and eyes. Its main function is to retain water to keep your tissues well lubricated and moist.
Skin wrinkles are formed under the influence of various factors, such as ageing, ultraviolet (UV) light and dryness. In particular, the degradation of collagen and HA by UV damage causes wrinkles.
The quantity of HA in the skin gradually decreases due to ageing and at the same time, HA content in the skin is considered to be related to the factors that cause wrinkles. The effect on skin wrinkles through the use of oral HA is expected because the decrease of skin damage leads to relieving of skin wrinkles. In addition, dry skin has been shown to be improved by oral ingestion of HA.
This study aims to test the skin anti-ageing effect of a synergistic skin anti-aging treatment (active oral food supplement + active topical cosmetic product) based on an innovative Full Spectrum-Hyaluronan (STAR&DIFFERENCE).

Who can participate?
Healthy women aged 35 to 70 years who are willing to take part

What does the study involve?
Participants will be randomly allocated to receive either both the active HA cosmetic and food supplements or to receive placebo cosmetic and active food supplements or active cosmetic and placebo food supplements for 28 days. Participants will be assessed up to 14 days after the 28 days supplement period.

What are the possible benefits and risks of participating?
Benefits associated with product use are amelioration of skin ageing signs.
Risks associated with the products intake/application are considered from low to very low, in absence of allergy/intolerances to products ingredients; other ingredients in the formula of the product are commonly used in dietary supplements. All the carried out instrumental

measurements are not invasive and no skin side effects are expected from the measurement process.

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

When is the study starting and how long is it expected to run for?
September 2020 to February 2021

Who is funding the study?
Complife Italia SRL (Italy)

Who is the main contact?
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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.NAA00.085.04.01_2019_2019/2657- VERSION N° 0 – 01st August 2019

Study information

Scientific Title
Assessment of the skin anti-aging efficacy of a synergic treatment (food supplement and cosmetic product) based on a new full spectrum hyaluronan. A double-blind, randomized, placebo-controlled clinical study

Acronym
STAR&DIFFERENCE

Study objectives
The adoption of a synergistic skin anti-aging treatment (active oral food supplement + active topical cosmetic product) based on a wide spectrum of hyaluronans is effective and safe in ameliorating aging-related clinical signs of skin

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/09/2020; Independent Ethical Committee for Non-Pharmacological Clinical Study Trials (Società Scientifica Italiana per le Indagini Cliniche Non Farmacologiche, Via XX Settembre 30/4, 16121 Genova, Italy; +39(0)10 5454842; a.scudieri@studinonfarmacologici.it); ref: 2019/09

Study design
Multicenter interventional double-blinded randomized placebo-controlled parallel-group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Home

Study type(s)
Other

Participant information sheet
See additional file (in Italian)

Health condition(s) or problem(s) studied
Skin ageing and its effects on skin hydration, elasticity/firmness and profilometry

Interventions
A double-blind, randomized, placebo-controlled clinical study is carried out on 3 groups of 25 subjects each as follows:
G1 use placebo cosmetic product + active food supplement for 28 days
G2 use the active cosmetic product + the food supplement placebo for 28 days
G3 use the complete active treatment (active cosmetic product + active food supplement) for 28 days
Participants were followed up for 42 days

Randomization
A restricted randomization list is generated by the in-site Study Director using an appropriate statistic algorithm (“Wey’s urn”). For each subject participating in the study are prepared an envelope containing the information on the product tested. Both the randomization list and the subjects envelopes are stored by the in-site Study Director under appropriate safety conditions in a place that is not accessible neither to volunteers nor to the experimenter.

Intervention Type
Supplement

Primary outcome measure
1. Determination of the Skin moisturization, evaluated as skin moisturization index using a Corneometer® and as Gray Index using MoistureMap MM 100 at baseline and after 14, 28 and 42 days
2. Determination of skin elasticity and firmness, based on the suction/elongation method and the subsequent release of the skin using Cutometer® at baseline and after 14, 28 and 42 days
3. Determination of skin profilometry, measuring wrinkle depth and skin roughness using Primos 3D at baseline and after 14, 28 and 42 days
4. Acquisition of face digital pictures using a reflex digital camera at baseline and after 14, 28 and 42 days

Secondary outcome measures
Products tolerability, efficacy, and acceptability evaluated using a self-assessment questionnaire administered after 4 weeks (T28), and after a 14 days wash-out from oral treatment (T42)

Overall study start date
21/09/2020

Completion date
26/02/2021

Eligibility

Key inclusion criteria
1. Good general health
2. Females of caucasian ethnicity
3. Photoype I to IV
4. Age between 35 and 70 years old
5. Mild/moderate signs of ageing (mild/moderate Crow's feet wrinkles and mild/moderate face slackness)
6. Subjects who have not been recently involved in any other similar study
7. Willingness to use for face care only the creams that will be consigned at the beginning of the study
8. Willingness to submit before and after pictures
9. Willingness to use during all the study period only the products to be tested
10. Willingness not to use similar products that could interfere with the product to be tested
11. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, etc.)
12. Subject is under effective contraception (oral/not oral); not expected to be changed during the trial
13. Subject aware of the study procedures and having signed an informed consent form
14. Subjects who accept not to expose themselves in an intensive way to UV rays during the whole study duration

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
75

Total final enrolment
75

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Pregnant/breastfeeding female or who have planned pregnancy during the study period
3. Positive history for atopy or hypersensitive skin
4. Subjects under systemically pharmacological treatment
5. Subjects under locally pharmacological treatment on the skin area monitored during the test
6. Subjects with congenital or acquired immunodeficiency
7. Subjects under treatment with food supplements which could interfere with the functionality of the product under study
8. Subjects which show other skin alterations on the monitored area
9. Subjects considered as not adequate to participate in the study by the investigator
10. Subjects with known or suspected sensitization to one or more test formulation ingredients
11. Adult protected by law (under control or hospitalized in public or private institutions for

reasons other than research, or incarcerated)
12. Subjects not able to communicate or cooperate with the investigator for problems related to language, mental retardation or impaired brain function

Date of first enrolment
01/12/2020

Date of final enrolment
08/01/2021

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia Srl
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Sponsor information

Organisation
Complife Italia Srl

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Complife Italia Srl

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-review journal.

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. 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 v2	03/09/2019	04/01/2021	No	Yes
Results article		27/05/2022	24/08/2022	Yes	No