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Reverse the clock: a clinical trial of collagen activator effects on biological age and skin quality

Submission date
03/07/2025

Recruitment status
No longer recruiting

Registration date
05/07/2025

Overall study status
Completed

Last Edited
04/07/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Skin aging is a complex process that involves both intrinsic and extrinsic factors. Intrinsic factors, such as genetic and hormonal changes, play a role in skin aging, while extrinsic factors, such as exposure to UV radiation and environmental toxins, accelerate the aging process. The signs of skin aging include wrinkles, age spots, reduced elasticity, reduced hydration, and increased transepidermal water loss. As we age, the body's natural ability to replenish collagen decreases by approximately 1.0%-1.5% per year. This decline in collagen production is a significant factor contributing to the development of fine lines and deeper wrinkles. Additionally, within the deeper layers of the skin (dermis), essential components of the extracellular matrix such as fibrillar collagens, elastin fibers, and hyaluronic acid undergo noticeable structural and functional changes.
The aging process brings about various changes in the different layers of the skin. In the outermost layer, the epidermis, the thin basal lamina that separates it from the dermis becomes thinner, resulting in reduced cell turnover and a thinner epidermis. This leads to decreased barrier function, slower recovery, increased water loss, reduced hydration, and increased stiffness.
Epigenetic methylation clocks are emerging as a promising biomarker of biological age. DNA methylation is a chemical modification of DNA that regulates gene expression and plays a critical role in development and aging. Methylation patterns change over time, and researchers have developed epigenetic clocks based on DNA methylation patterns to estimate biological age.
The aim is to investigate whether the intake of the collagen activator from Avea for 6 months will result in a significant decrease in biological age compared to the baseline, and will lead to a significant
improvement in skin quality and texture, including increased hydration, elasticity, and reduction in wrinkles, pigmentation, texture, UV-spots, pores, redness, and porphyrins after 3 months compared to baseline.

Who can participate:
healthy adults over the age of 35 years, regardless of
gender or ethnicity, who are willing and able to give their informed consent to participate in the study.

What does the study involve?
- 3 on-site visits (Baseline, Month-1, and Month-3)
- Monthly Questionnaires
- 2 Saliva tests (baseline & Month-6) to measure biological age

What are the possible benefits and risks of participating?
The benefits for participants of the projects are the following:
Participants in this study stand to benefit by receiving information about their biological age and their skin quality, which has the potential to improve their welfare and health awareness.
These benefits are not only valuable to participants in the short term, but could also have important long-term health implications. By providing participants with free valuable health information, the study team is helping to promote participant welfare and ensure that the project is conducted in an ethical and responsible manner.
Risks:
Avea collagen activator (exposure)
As of now there are no known adverse reactions associated with the product from any of the early trials and since the product has been on the market, there have been no reports of major adverse effects or reactions.
Skin analysis (Corneometer, cutometer, ultrascan (22Mhz), Visia scan:
Risk minimisation during the recruitment process through screening for any sensitivity regarding exposure to light (sunlight, UV-light etc.)
A medical professional is accompanying the trial participant during that process and on the lookout for any adverse reactions or complications during the process
All procedures that are part of the skin analysis are non-invasive. In rare cases they can lead to skin irritation or damage, specifically if they are used too often or with too
much pressure, which our study personal will be instructed to avoid.
All skin tests will not be performed on open wounds or skin infections.
Saliva collection:
The risks are minimized as the sample collection is non-invasive (participant spits on a clean spoon).
The sample collection is self-administered and participants will be provided with clear and concise instructions on how to collect their saliva sample.

Where is the study run from:
Hautwerk Dermatology Clinic, Zurich (Switzerland)

When is the study starting, and how long is it expected to run from?
October 2023 to October 2024.

Who is funding the study?
The project is industry funded through the sponsor, Avea life AG (Switzerland)

Who is the main contact?
Matilde Mantovani, Avea Life AG, matilde@avea-life.com
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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2023-00953

Study information

Scientific Title
Reverse the clock: a clinical trial of collagen activator effects on biological age and skin quality

Study objectives
Primary objective: Intake of the collagen activator from Avea for 6 months will result in a significant decrease in biological age compared to the baseline.
Secondary objective: Intake of the collagen activator from Avea will lead to a significant improvement in skin quality and texture, including increased hydration, elasticity, and reduction in wrinkles, pigmentation, texture, UV-spots, pores, redness, and porphyrins after 3 months compared to baseline.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/09/2023, Kantonale Ethikkommission Zürich (Stampfenbachstrasse 121, Zurich, 8090, Switzerland; +41 432597970; info.kek@kek.zh.ch), ref: 2023-00953

Study design
Single-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records, Other

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Efficacy of Collagen supplementation in improving skin quality and reducing the signs of skin aging.

Interventions

The study is a human research study in which customers that are taking the collagen activator from Avea are observed for six months. The trial is in the form of a post marketing surveillance observational trial since the product has already been approved and is sold on the market. All participants are voluntarily taking the collagen activator. There is no blinding, randomization or placebo control that is taking place in the trial. The results are compared individually for each participant after the follow ups from their baseline measurements.

The trial exposure is the Collagen activator from Avea

- Potential participants are contacted after purchasing the collagen activator for 6 months via Avea's online shop. After successful recruitment they undergo the baseline assessment. They are instructed to only start taking the collagen activator once the baseline assessment is completed.
- Daily oral intake of 1 package of 11.5g diluted in water over six months, taken in the morning

Saliva samples are taken twice (time points 0 and +6 months) to determine biological age via epigenetic methylation clock (Trume labs are the test providers and analysers)

Skin analysis takes place at time points 0, +1 and +3 months to determine skin quality. This includes measurements of hydration, elasticity, skin thickness and density, as well as pigmentation, wrinkles, texture, UV-spots, pores, redness and porphyrins.

Skin tests used for this are the corneometer, cutometer, ultrascan and Visia scan.

Every month the participants receive a questionnaire regarding recent subjective changes, adverse reactions and adherence.

The project population consists of healthy adults over the age of 35 years, regardless of gender or ethnicity, who are willing and able to give their informed consent to participate in the study. The total number of participants will be 60.

Intervention Type

Supplement

Primary outcome measure

Changes in DNA methylation patterns as a biomarker of biological age using TruMe DNA test at Baseline and Month-6.

Secondary outcome measures

1. Hydration, measured using the corneometer at Baseline, Month-1, and Month-3.
2. Elasticity, measured using the cutometer at baseline, Month-1, and Month-3
3. Skin thickness and density, measured using the ultrascan at baseline, Month-1, and Month-3.
4. Pigmentation, wrinkles, texture, UV-spots, pores, redness, and porphyrins, measured usign the Visia scan at baseline, Month-1, and Month-3.

These measurements contribute to determining skin quality and texture by providing objective and quantitative data on various aspects of the skin. By monitoring changes in these measurements over time, researchers can assess the effectiveness of the collagen activator aimed at improving skin quality and texture.

Overall study start date

19/09/2023

Completion date

14/10/2024

Eligibility

Key inclusion criteria
1. Age 35 or older, regardless of gender, ethnicity or socioeconomic background
2. Voluntarily purchasing the collagen activator (from Avea) for 6 months with the intend to take it on a daily basis
3. Willing to fill out the questionnaires on a monthly basis.
4. Willing to participate in all measurements part of the study (Skin tests & saliva samples)
5. Able to appear at the baseline, 1 and 3 months follow-up visits at the Dermatology clinic “Hautwerk” in Zürich

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
35 Years

Sex
Both

Target number of participants
100

Total final enrolment
66

Key exclusion criteria
1. Underlying health conditions leading to regular intake of medication, including:
1.1. Diabetes
1.2. Hypertension (high blood pressure)
1.3. Cardiovascular disease
1.4. Asthma
1.5. Chronic obstructive pulmonary disease (COPD)
1.6. Arthritis
1.7. Depression
1.8. Anxiety
1.9. Epilepsy
1.10. Cancer
1.11. Thyroid disorders
1.12. Autoimmune diseases (e.g., lupus, multiple sclerosis)
1.13. Chronic kidney disease
1.14. Liver disease
1.15. HIV/AIDS
1.16. Chronic pain conditions (e.g., fibromyalgia, chronic migraine)
2. Chronic skin conditions, independent of treatment, including:

2.1. Acne
2.2. Eczema
2.3. Psoriasis
2.4. Rosacea
2.5. Skin cancer
3. Intake of any collagen supplements within 3 months prior to the screening date
4. Smoking at the time of recruitment or within 5 years prior
5. Pregnancy or lactating at the time of recruitment, or planning pregnancy within the next 6 months
6. Insufficient knowledge of the German or English language
7. Inability to give consent
8. Inability to follow study procedures

Date of first enrolment
02/10/2023

Date of final enrolment
09/11/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
Hautwerk dermatology clinic
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Sponsor information

Organisation
Avea Life AG

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Sponsor type

Industry

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Funder(s)

Funder type
Industry

Funder Name
Avea Life AG

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4	29/08/2023	04/07/2025	No	Yes
Protocol file	version 4	29/08/2023	04/07/2025	No	No