

Study of the effectiveness and tolerance of a food supplement in Anti-Aging Therapy

STUDY CODE: VIORICA-COD2-2024

<i>Made by</i>	<i>Sponsor</i>
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The investigation was conducted in accordance with the protocol, the ethical principles based on the latest current version of the Declaration of Helsinki, ICH Guidelines on Good Clinical Practice and applicable national and/or international legislation.

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1 CLINICAL STUDY DETAILS

A randomised, double-blind, placebo controlled clinical study was conducted on 70 female subjects with obvious signs of aging during the period May 13 - September 6, 2024. The study participants were divided into two arms, with each volunteer ingesting 30ml daily of either the real product “21Collagen, 480ml” or a placebo, for the duration of 13 weeks. Biometric measurements of skin’s parameters were performed at T0, T7, and T13.

The study was conducted by Dra. Ester Moreno Artero, Specialist in Dermatology, for the benefit of the sponsor Amaryne Biolabs S.R.L., under the approval of Ethics Committee for Clinical Research in Medicines and Medical Devices of University Hospital Príncipe de Asturias, at the research center Centro Médico Complutense grupo Virtus Complutum in Madrid, Spain

2 CLINICAL STUDY OBJECTIVES

Primary efficacy objective: demonstrate effectiveness as an aid in improving the signs and symptoms of skin aging.

Primary safety objective: to evaluate the safety of the treatment through the systematic recording and analysis of the serious adverse events (SAEs) detected during the study.

Secondary safety objective: to evaluate the safety of the treatment through the systematic recording and analysis of the adverse events (AEs) detected during the study.

3 CLINICAL STUDY RESULTS AND CONCLUSIONS

The product “21Collagen, 480 ml” **is very good at improving elasticity in facial skin,** having demonstrated a statistically significant improvement in elasticity both compared to T0 and to the placebo. Biometric measurement of volunteers’ skin using CUTOMETER® probe has demonstrated:

- **32.11% average increase in elasticity after 7 weeks** of 21Collagen product
- **27.75% average increase in elasticity after 13 weeks** of 21Collagen product

Regarding subjective evaluation by the study participants, the product “21Collagen, 480 ml” has received a good rating from the volunteers, with 77% of the subjects considering that it improves the overall appearance of their skin.

The product has **a high level of tolerance and an adequate safety profile**, with no serious and unexpected adverse events occurring.

The following results were also observed on select participants after 13 weeks:

- *Up to 146.36% improvement in skin hydration (as measured by MoistureMAP®)*
- *Up to 58.79% improvement in forehead wrinkle volume (as measured by AEVA-HE®)*
- *Up to 38.37% improvement in wrinkle density (as measured by AEVA-HE®)*
- *Up to 54.52% improvement in skin firmness (as measured by CUTOMETER®)*
- *Up to 30.59% improvement in skin barrier function (as measured by TEWAMETER®)*

4 SIGNATURES

Principal researcher:

Ester Moreno Artero



February 10, 2025

CRO Representant:

Ramón Goya Gato.



February 10, 2025

Sponsor:

Josan Natalia.

February 10, 2025