

Cover Page

Official Title: Impact of Oral Supplementation of Specific Bioactive Collagen Peptides on Human Skin Physiology: A Randomized, Double-Blind, Placebo-Controlled Trial

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1. Study Protocol (Short Form)

1.1 Background and Rationale

Skin aging is a multifactorial biological process influenced by intrinsic physiological changes (chronological aging, hormonal decline, genetic factors) and extrinsic environmental factors (UV exposure, pollution, lifestyle). Collagen is a key structural protein in the dermis, essential for maintaining elasticity and integrity. Oral supplementation with specific bioactive collagen peptides (SCP) has been proposed as a non-invasive intervention to support dermal structure, hydration, and wrinkle reduction.

1.2 Study Objectives

- **Primary Objective:** Evaluate the effect of 8-week oral SCP supplementation on stratum corneum hydration (SCH) in healthy adult women.
- **Secondary Objectives:** Assess effects on transepidermal water loss (TEWL), skin elasticity (R2, R5), skin firmness (F4), collagen content (2 mm depth), periorbital wrinkle morphology (area, volume, depth), and subjective skin assessment.

1.3 Study Design

- Type: Single-center, prospective, randomized, double-blind, placebo-controlled clinical trial
- Duration: 8 weeks
- Visits: Baseline (Week 0), Week 4, Week 8
- Intervention: 2.5 g SCP (VERISOL®) daily or matching placebo
- Randomization: 1:1 ratio, computer-generated list, blinding maintained for participants and investigators

1.4 Study Population

- **Sample Size:** 66
- **Inclusion Criteria:** Healthy women aged 35–55, Fitzpatrick skin type III–IV, specific grading of crow's feet and under-eye fine lines
- **Exclusion Criteria:** Recent use of anti-inflammatory medication, pregnancy/lactation, dermatologic conditions, recent aesthetic procedures, systemic diseases affecting skin, allergy to study product

1.5 Study Procedures

- **Physiological Measurements:** SCH, TEWL, skin elasticity (R2, R5), firmness (F4), collagen content (SIAscope)
- **Wrinkle Morphology:** 3D imaging (Derma TOP) and standardized facial imaging (VISIA-CR)
- **Subjective Assessment:** Visual Analogue Scale (VAS) for skin texture, glossiness, smoothness, elasticity, and wrinkle appearance
- **Safety Monitoring:** Recording of adverse events, participant self-reporting, and clinical observation
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1.6 Study Product

- **Treatment:** VERISOL®, SCP derived from bovine type I collagen, 2.5 g/day
- **Placebo:** Maltodextrin, matched for appearance, taste, and texture
- **Administration:** Dissolved in warm water once daily

1.7 Statistical Analysis

- Repeated-measures ANOVA for primary and secondary endpoints
- Baseline comparisons: independent-samples t-tests or Mann–Whitney U tests as appropriate
- Within-group analyses: repeated-measures ANOVA with Bonferroni correction
- Rank transformation applied for non-normal endpoints
- Effect size: partial eta-squared (η^2) thresholds of 0.01 (small), 0.06 (medium), 0.14 (large)
- Significance: two-sided, $p < 0.05$

1.8 Ethical Considerations

- Conducted under the Declaration of Helsinki
- Approval: Shanghai Ethics Committee for Clinical Research (Approval No. SECCR2024-97-01)
- Informed consent obtained from all participants

Note: This document contains only study protocol and design details. No study results or participant-identifying information are included.