

A study testing whether collagen powder helps improve skin

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		<input type="checkbox"/> Protocol
Registration date 01/09/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/09/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Dietary consumption of food supplements has been found to modulate skin functions and can therefore be useful in the treatment of skin aging. Prior studies have demonstrated that oral intake of bioactive collagen peptides can reduce skin wrinkles, improve skin elasticity, and have positive effects on dermal matrix synthesis. This study was conducted to assess the effect on facial skin appearance of a collagen powder supplement when consumed daily for 8 weeks by women with mild to moderate periorcular fine lines and wrinkles, and fine lines, wrinkles, sagging, and lack of radiance on the global face.

Who can participate?

Adult female healthy volunteers aged over 45 years

What does the study involve?

Participants were randomly assigned to either a dummy (placebo) supplement group or a collagen supplement group. Participants consumed the assigned supplement once per day. The participants were instructed to stir one scoop (2.6g) of the test product into a hot or cold beverage and consume, once daily. They could take the product at any time of the day, before or with food. They stored the products in a cool, dry place that is away from direct heat and light (including sunlight) and protected from contamination.

They were also instructed to wash their face with the provided cleanser as they normally would, and not to use the cleanser if they normally don't wash their face with anything except water. Once daily, they could apply a sufficient amount of the provided moisturizer to the entire face. But they were instructed not to apply the moisturizer within 24 hours before a clinic visit.

What are the possible benefits and risks of participating?

Benefits

The primary anticipated benefit of this intervention is improved skin health. Collagen supplementation has been associated with enhancements in skin hydration, elasticity, and overall appearance in prior studies. Participants may therefore experience modest but measurable improvements in dermatological outcomes during the course of the trial.

Risks

The risks of participation are expected to be minimal. Collagen is generally recognized as safe, and adverse events are uncommon and typically mild (e.g., transient gastrointestinal discomfort). No serious risks are anticipated. Participants may not personally experience any benefit, but the knowledge gained from the study could contribute to a better scientific understanding of collagen's role in skin health.

Where is the study run from?

Wellness Discovery Labs, USA. Data was collected at SGS Stephens, Inc, Dallas Research Center, USA.

When is the study starting and how long is it expected to run for?

May 2022 to August 2022

Who is funding the study?

Specnova LLC, USA.

Who is the main contact?

Irina Lorenzi, irina@specnova.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Prof Heather Hausenblas

ORCID ID

<https://orcid.org/0000-0002-0127-9184>

Contact details

Wellness Discovery Labs
3535 Pine St
Jacksonville
United States of America
32205
+1 9048919746
hhausenblas@wellnessdiscoverylabs.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

SGS Stephens, Inc, number: C22-D090, protocol number: Pro00063299

Study information

Scientific Title

A double-blind, placebo-controlled clinical study to assess the skin benefits of a collagen powder supplement

Study objectives

This single-center, double-blind, randomized, placebo-controlled clinical trial was conducted for Specnova LLC to assess the effect on facial skin appearance of the Sponsor's collagen powder supplement when consumed daily for 8 weeks by women with mild to moderate periocular fine lines and wrinkles, and fine lines, wrinkles, sagging, and lack of radiance on the global face.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 03/05/2022, Advarra Institutional Review Board (6100Merriweather Drive, Suite600, Maryland, 21044, United States of America; +1 4108842900; institutions@advarra.com), ref: IRB#00000971

Study design

Double-blind randomized placebo-controlled clinical study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Internet/virtual, Laboratory, Telephone

Study type(s)

Efficacy

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Assess the effect on facial skin appearance of the collagen powder supplement when consumed daily for 8 weeks by women with mild to moderate periocular fine lines and wrinkles, and fine lines, wrinkles, sagging, and lack of radiance on the global face.

Interventions

The research team and study participants were blinded to the treatment assignment and were not made aware of receiving the placebo or the active product. Before the start of the study, SGS Stephens generated a randomization list to establish treatment assignment to 1 of the

treatment cells (cell 1 or cell 2). The list was first created by concatenating blocks of size 4 subjects: 2 for cell 1 and 2 for cell 2. The list was then randomized by variables from 2 independent uniform distributions: one to randomize subjects. Within a block and one to randomize blocks. After the randomization list was created, treatment was assigned to each subject number accordingly.

During the course of the study, subjects consumed the assigned supplement once per day as directed. The participants were instructed to stir one scoop (2.6g) of the test product into a hot or cold beverage and consume, once daily. They could take the product at any time of the day, before or with food. They stored the products in a cool, dry place that is away from direct heat and light (including sunlight) and protected from contamination.

Additionally, all subjects used the supporting materials (Gentle Skin Cleanser and Daily Facial Moisturizer with Sunscreen Broad Spectrum SPF 15) as directed.

At week 1, a clinic staff member called each subject to confirm that subjects were consuming the assigned supplement and using the supporting materials as instructed.

Clinical evaluations were conducted at visit 1 (baseline), visit 2 (week 4), and visit 3 (week 8). Subjects participated in the following procedures at each time point (unless otherwise indicated):

- **Clinical Grading of Efficacy Parameters**

Each subject was clinically graded for fine lines and wrinkles on the periocular area and global face; skin smoothness (visual) on the cheeks; and firmness (sagging) (visual), radiance, and overall appearance of skin condition (healthy) on the global face.

Additionally, triplicate pinch recoil measurements were performed on the left crow's feet area to assess skin elasticity/resiliency.

- **Digital Imaging Using Portrait Photo Station**

Full-face digital images were taken from each subject (left, center, and right views) using the SGS Stephens, Inc. portrait photo station with a Canon Mark II 7D digital SLR camera (Canon Incorporated, Tokyo, Japan) and a Canon EF-S 60mm f/2.8 macro lens under visible lighting mode.

- **Antera 3D Imaging**

Digital images were taken from each subject's left or right cheek, as determined by the grader, using Antera 3D® imaging (Miravex Ltd, Dublin, Ireland).

After study completion, images were analyzed for mean roughness (Ra).

- **Cutometer Measurements**

Duplicate measurements were taken from adjacent sites on each subject's right under-eye orbital bone using Cutometer MPA 580 (Courage + Khazaka electronic GmbH, Köln, Germany) to measure the viscoelastic properties of the skin.

- **Self-assessment Questionnaire**

At week 8, subjects completed a Sponsor-provided self-assessment questionnaire regarding skin improvements and product perception.

Intervention Type

Supplement

Primary outcome measure

The following primary outcome measures were assessed at clinical evaluations conducted at visit 1 (baseline), visit 2 (week 4), and visit 3 (week 8):

1. Clinical Grading of Efficacy Parameters: Each subject was clinically graded for fine lines and wrinkles on the periocular area and global face; skin smoothness (visual) on the cheeks; and firmness (sagging) (visual), radiance, and overall appearance of skin condition (healthy) on the global face.
2. Skin elasticity/resilience was measured using triplicate pinch recoil measurements performed on the left crow's feet area

Secondary outcome measures

The following secondary outcome measures were assessed at clinical evaluations conducted at visit 1 (baseline), visit 2 (week 4), and visit 3 (week 8), unless stated:

1. Mean skin roughness was measured using the following digital images after study completion:
 - 1.1. Full-face digital images captured using SGS Stephens, Inc. portrait photo station with a Canon Mark II 7D SLR camera and a Canon EF-S 60mm f/2.8 macro lens under visible lighting mode
 - 1.2. Cheek images captured using Antera 3D® imaging system
2. Viscoelastic properties of adjacent skin sites on each subject's right under-eye orbital bone the skin were measured using a Cutometer MPA 580
3. Skin improvements and product perception were measured using a Sponsor-provided self-assessment questionnaire at week 8

Overall study start date

19/05/2022

Completion date

22/08/2022

Eligibility

Key inclusion criteria

Women

Participant type(s)

Healthy volunteer

Age group

Mixed

Lower age limit

45 Years

Upper age limit

71 Years

Sex

Female

Target number of participants

90

Total final enrolment

89

Key exclusion criteria

Women with limited fine lines and facial wrinkles

Date of first enrolment

19/05/2022

Date of final enrolment

19/08/2022

Locations

Countries of recruitment

United States of America

Study participating centre

SGS Stephens, Inc

Dallas Research Center

1801 North Glenville Drive, Suite 20

Richardson

United States of America

75081

Sponsor information

Organisation

Specnova LLC

Sponsor details

8609 Westwood Center Drive #110

Tysons Corner

United States of America

22182

+1 9048919746

irina@specnova.com

Sponsor type

Industry

Website

<https://specnova.com/>

Funder(s)

Funder type

Other

Funder Name

Naomi Whittel

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/11/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Irina Lorenzi, irina@specnova.com. Informed consent was obtained.

IPD sharing plan summary

Available on request