

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Safety and efficacy of assessment of Alis collagen drink (containing 4 g hydrolyzed collagen) compared to a control collagen-free drink for improvement of biophysical and ultrasonography skin parameters

Protocol summary

Study aim

Safety and efficacy of assessment of Alis collagen drink (containing 4 g hydrolyzed collagen) compared to a control collagen-free drink for improvement of biophysical and ultrasonography skin parameters.

Design

It is an interventional study as a randomized double blinded clinical study. 30 healthy adult volunteers will participate enrolled in the study after signing informed consent. Simple randomization is performed to assign each participant, using blind cards. In this way, the name of the formulation is written on the same cards. A card is selected randomly for each person.

Settings and conduct

The study will be conducted in Center for Research & Training in Skin Diseases and Leprosy. Volunteers in two separate groups consume 250ml of collagen-containing and collagen-free drinks daily for two weeks. The assessments of skin biophysical parameters (skin elasticity, Skin thickness and density and changes in stratum corneum hydration) will be performed before intervention and 4, 8 and 12 weeks after using. Then the changes in each parameter are compared in different groups. Participant blindness performed packing products in similar containers with different numeric code. For assessor blinding, the randomization list is given to a third person. Formulation to the participants assigned after receiving the randomization code by researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 35 to 55, Healthy people with skin type II to V, Signing the consent form for participation in the study. Exclusion criteria: History of using RF, anti-aging and intense pulsed light during the past 6 months, Active smoker in last 2 years

Intervention groups

Intervention group: daily consumption of 250 ml of Alis

collagen supplement drink for 8 weeks Control group: daily consumption of 250 ml of a drink without collagen for 8 weeks

Main outcome variables

Changing in skin elasticity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N22**

Registration date: **2023-09-20, 1402/06/29**

Registration timing: **prospective**

Last update: **2023-09-20, 1402/06/29**

Update count: **0**

Registration date

2023-09-20, 1402/06/29

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

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firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-01-20, 1402/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Safety and efficacy of assessment of Alis collagen drink (containing 4 g hydrolyzed collagen) compared to a control collagen-free drink for improvement of biophysical and ultrasonography skin parameters

Public title
Safety and efficacy of assessment of Alis collagen drink (containing 4 g hydrolyzed collagen) compared to a control collagen-free drink

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 35 to 55 Healthy people with skin type II to V
Signing the consent form for participation in the study

Exclusion criteria:

History of using RF, anti aging and intense pulsed light during the past 6 months .Active smoker in last 2 years
Pregnancy or lactating Suffering from systemic diseases that affect skin health, such as vascular collagen diseases, diabetes, hypothyroidism, as well as liver and kidney failure. History of taking supplements containing collagen, hyaluronic acid and vitamin C in the last 3 months

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by simple randomization using a blind card, In this way, the name of the formulation is written on the same cards. A card is selected randomly for each person.

Blinding (investigator's opinion)

Double blinded

Blinding description

In case of assessor blinding, the randomization list is given to a third person. Assignment of the formulation to participants is made after receiving the code of randomization by researcher. Participant blindness performed packing products in similar containers with different numeric code.

Placebo

Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-09-05, 1402/06/14

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.076

Health conditions studied

1

Description of health condition studied

skin aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Skin elasticity

Timepoint

Before intervention , 4, 8 and 12 weeks after using

Method of measurement

Cutometry

Secondary outcomes

1

Description

Skin thickness and density

Timepoint

Before intervention ,4 , 8 and 12 weeks after using

Method of measurement

Skin ultrasound

2

Description

Changes in stratum corneum hydration

Timepoint

Before intervention , 4, 8 and 12 weeks after using

Method of measurement

Corneometry

Intervention groups

1

Description

Intervention group: daily consumption of 250 ml of Alis collagen supplement drink for 8 weeks, which includes: Spring water, hydrolyzed bovine collagen protein (food grade) 4g, acerola powder-vitamin A (0.0066 gr/lit), vitamin C (1 gram of acerola powder with 32% purity of vitamin C has been added in the formulation), vitamin E (0.75 gr/lit and hyaluronic acid (0.022gr)

Category

Treatment - Drugs

2

Description

Control group: daily consumption of 250 ml of collagen-free drink for 8 weeks, which includes: Spring water, acerola powder-vitamin A (0.0066 gr/lit), vitamin C (1 gram of acerola powder with 32% purity of vitamin C has been added in the formulation), vitamin E (0.75 gr/lit and hyaluronic acid (0.022gr)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Naderi Aven., Taleghani St.

City

Tehran

Province

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Postal code

1416613675

Phone

+98 21 8897 2220

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pishgamane Eixire Sabze Arvand Co.

Full name of responsible person

Nasrin Fayyaz

Street address

No. 108, 3rd Taleghani, Ahmed Abad Street, Mashhad

City

Tehran

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9176755149

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info@idcalis.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pishgamane Eixire Sabze Arvand Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

MD and Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Dermatologist and professor of Tehran University of Medical Sciences.

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable