Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

Cutometery

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
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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
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9176755149
Phone
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Email
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
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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
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Full name of responsible person
Maryam Ahmadi

Position
Researcher

Latest degree
Master

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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