

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Safety and efficacy of oral supplement sachet of "Collagen Gold" in improving biophysical parameters and skin ultrasound indexes

Protocol summary

Study aim

Safety and efficacy of oral supplement sachet of "Collagen Gold" in improving biophysical parameters and skin ultrasound indexes

Design

Single group, phase 2, before -after clinical study. sample size is 19. The study is not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 19 healthy volunteers with skin wrinkle will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use oral supplement sachet of "Collagen Gold" for 12 weeks once in a day. Before intervention , 6 and 12 weeks after using changing in skin will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 40 to 65, 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

Intervention groups

Daily consumption of a supplement sachet with Collagen Gold brand for 12 weeks contains: 5000 mg of hydrolyzed collagen types 1 and 3, 50 mg hyaluronic acid, 80 mg of vitamin C.

Main outcome variables

Change in skin elasticity, Skin thickness and density and changes in stratum corneum hydration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N17**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of oral supplement sachet of "Collagen Gold" in improving biophysical parameters and skin ultrasound indexes

Public title

Safety and efficacy of oral supplement sachet of "Collagen Gold"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 40 to 65 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

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **19**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.973

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 , 6 and 12 weeks after using

Method of measurement

Cutometry

Secondary outcomes**1****Description**

Skin thickness and density

Timepoint

Before intervention , 6 and 12 weeks after using

Method of measurement

Skin ultrasound

2**Description**

changes in stratum corneum hydration

Timepoint

Before intervention , 6 and 12 weeks after using

Method of measurement

Corneometry

Intervention groups**1****Description**

Intervention group: daily consumption of a supplement sachet with Collagen Gold brand for 12 weeks contains: 5000 mg of hydrolyzed collagen types 1 and 3, 50 mg hyaluronic acid, 80 mg of vitamin C.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

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No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Adrian Salamat Medicine Development Company
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Adrian Salamat Medicine Development Company
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
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Latest degree
Ph.D.
Other areas of specialty/work

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Person responsible for updating data

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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