

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Formulation of Dietary Supplement Using Collagen, Ornithine and Probiotic and its Evaluation on Skin Health Factors in Healthy People: A Double-Blind Randomized Controlled Trial

Protocol summary

Registration timing: **prospective**

Study aim

Design of dietary supplement containing collagen, ornithine and probiotics and its evaluation on skin health indicators in two groups of intervention and control

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Design

Two arm parallel-group randomised trial with blinded postoperative care and outcome assessment

Registrant information

Name

Fardin Javanmardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7483

Email address

f.javanmardy@gmail.com

Settings and conduct

Information will be provided for the entry of people with inclusion and exclusion criteria by installing announcements in medical and health centers under the supervision of Shahid Beheshti University of Medical Sciences. Then, the individuals will be divided into two groups of 37 by random block method (blocks with a volume of at least 4 to prevent the blinding of the study to be revealed).

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Age range 20-60 years • Do not have any allergies • Willingness to enter the study • No supplementation in 6 months before
Exclusion criteria: • Having any chronic disease • Having any allergies (whether food or non-food) • People with digestive problems

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-23, 1400/06/01

Intervention groups

Intervention group: People who will receive collagen, ornithine and probiotic supplements
Control group: People who will receive a maltodextrin supplement

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Skin health

Trial completion date

empty

General information

Scientific title

Formulation of Dietary Supplement Using Collagen, Ornithine and Probiotic and its Evaluation on Skin Health Factors in Healthy People: A Double-Blind Randomized Controlled Trial

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201226049840N1**

Registration date: **2021-04-13, 1400/01/24**

Public title

Designing a Dietary Supplement to Promote Skin Health

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 20-60 years Lack of any allergies Desire to include the study Do not take supplements at 6 months ago

Exclusion criteria:

Suffering from any chronic disease Having any allergies (food or non-food) People with digestive problems

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: Individuals will be assigned to intervention and placebo groups using cards marked 'A' or 'B'. Codes A and B will be written in 70 numbers. So there will be 35 cards A and 35 cards B. After visiting each volunteer, one of these cards will be randomly selected, which will be indicated on the volunteer number card and its group type.

Blinding (investigator's opinion)

Double blinded

Blinding description

None of the people involved in the study, nor any of the interveners, will be aware of the type of intervention being performed on the individuals. The placebo will be completely similar to the formulated powder in terms of appearance, texture and taste, because the same essential oil and color will be used in the placebo and the optimized formula.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Institute of Nutritional Research and Food Industry

Street address

Qods Town(the West), Shahid Farahzadi Blvd, Shahid Hafezi St

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.SBMU.nnftri.Rec.1400.001

Health conditions studied

1

Description of health condition studied

Healthy subjects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Skin PH

Timepoint

Before and after 60 days intervention

Method of measurement

PH meter

2

Description

Elasticity

Timepoint

Before and after 60 days of the intervention

Method of measurement

Cotometer

3

Description

Skin moisture

Timepoint

Before and after 60 days of the intervention

Method of measurement

Cornimeter

4

Description

Trans-epidermal water loss

Timepoint

Before and after 60 days of intervention

Method of measurement

Tonometer

5

Description

Skin pigments

Timepoint

Before and after 60 days of the intervention

Method of measurement

Mexameter

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before and after 60 days of intervention

Method of measurement

Scale and meter

Intervention groups

1

Description

Intervention group: In this group, on the first day, skin health indicators such as moisture, pH, elasticity, pigment and water loss through the epidermis will be measured. Then, the participants will be trained which dissolve 1 sachet containing collagen, ornithine and probiotic compounds in 200 ml of milk or water daily and eat it as a snack. One sachet will be consumed daily for 60 days during the intervention. Then, at the end of the study, the mentioned skin health indicators will be measured again.

Category

Prevention

2

Description

Control group: In this group, on the first day, skin health indicators such as moisture, pH, elasticity, pigment and water loss through the epidermis will be measured. Then, the participants will be trained which dissolve 1 sachet of maltodextrin compounds (22 g) in 200 ml of milk or water daily and eat it as a snack. One sachet will be consumed daily for 60 days during the intervention. Then, at the end of the study, the mentioned skin health indicators will be measured again.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Dolat Dermatology Clinic

Full name of responsible person

Dr. Alireza Firooz

Street address

Daman Afshar Street, Valiasr Avenue, TEHRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Amir Mohammad Mortazavian

Street address

Qods Town(the West), Shahid Farahzadi Blvd.,
Shahid Hafezi St.(Western Purple)

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fardin Javanmardi

Position

Ph.D student
Latest degree
Master
Other areas of specialty/work
Food Technology and Quality Control
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be provided to researchers after analysis
and summarization

When the data will become available and for how long

Starting access to results after publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

There are no restrictions on the use of data

From where data/document is obtainable

They should contact with email address:
f.javanmardy@gmail.com

What processes are involved for a request to access data/document

There is no time limitation

Comments