

# 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

### **City**

Tehran

### **Province**

Tehran

### **Postal code**

65183 -19697

### **Phone**

+98 21 8888 4196

### **Email**

info@iranderm.net

## **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 )

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1981619573

#### **Phone**

+98 21 2235 7483

#### **Email**

info@nnftri.ac.ir

### **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  
**Street address**  
Qods Town( the West ), Shahid Farahzadi Blvd.,  
Shahid Hafezi St  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1981619573  
**Phone**  
+98 21 6688 0696  
**Email**  
f.javanmardy@gmail.com

## Person responsible for scientific 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**  
Ph.D.  
**Other areas of specialty/work**  
Food Technology and Quality Control  
**Street address**  
National Nutrition and Food Technology Research  
Institute (NNFTRI), West Arghavan St. Farahzadi Blvd.,  
Sharake Qods, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1981619573  
**Phone**  
+98 21 2235 7483  
**Fax**  
**Email**  
f.javanmardy@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**

Fardin Javanmardi  
**Position**  
Ph.D student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Food Technology and Quality Control  
**Street address**  
National Nutrition and Food Technology Research  
Institute (NNFTRI), West Arghavan St. Farahzadi Blvd.,  
Sharake Qods, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1981619573  
**Phone**  
+98 21 2235 7483  
**Fax**  
**Email**  
f.javanmardy@gmail.com

## 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