

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of the egg white protein and zinc-enriched synbiotic supplement and placebo on the muscle strength, muscle mass and quality of life in older adults with sarcopenia

Protocol summary

Study aim

The aim of this study is to determine the Effects of egg white protein (Albumen) and zinc-enriched synbiotic supplement on the muscle strength, muscle mass and quality of life in older adults with sarcopenia.

Design

A double blind, randomized with permuted block randomization, controlled clinical trial with a parallel group design (phase 3) on 72 patients

Settings and conduct

Sampling are performed among the elderly aged 65 and older who refer to 6 medical centers in Shiraz and then sarcopenia is evaluated in the bone densitometry department of Namazi Hospital in Shiraz. Participants, researchers, and outcome assessors were blinded through apparent similarity of the intervention and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 65 years and older; Sarcopenia diagnosis according to European Working Group on Sarcopenia in Older People (EWGSOP) guidelines; using calcium and vitamin D supplements. Non-Inclusion criteria: Subjects with history of chronic disease (e.g. Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disorder (COPD), Chronic Renal Failure (CRF), cirrhosis liver failure, active cancer, uncontrolled diabetes and stroke.

Intervention groups

Intervention group: Participants in intervention group consume egg white protein and zinc-enriched synbiotic supplement, daily for 8 weeks. Control group: Participants in control group consume daily placebo powder for 8 weeks

Main outcome variables

Appendicular Skeletal Muscle Mass; Skeletal Muscle Mass Index (SMI); Hand Grip Strength (HGS); Weight; BMI; Waist circumference; Calf circumference; Arm

circumference; Fat mass; Percent of Fat; Gynoid fat mass; Android fat mass; Quality of life; Physical performance (SPPB); Fasting Blood sugar (FBS) level; Lipid profile (LDL, HDL, Triglyceride, total cholesterol)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220414054536N1**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Marzieh Mahmoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1007

Email address

marzieh.mahmoodi123@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of the egg white protein and zinc-enriched synbiotic supplement and placebo on the muscle strength, muscle mass and quality of life in older adults with sarcopenia

Public title
Effect of egg white protein and zinc-enriched synbiotic supplement in Sarcopenic Elderly

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women aged 65 years and older Sarcopenia diagnosis according to European Working Group on Sarcopenia in Older People (EWGSOP) guidelines using calcium and vitamin D supplements
Exclusion criteria:
Subjects with history of chronic disease (e.g. Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disorder (COPD), Chronic Renal Failure (CRF), cirrhosis liver failure and active cancer. Subjects with history of uncontrolled diabetes and stroke.

Age
From **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of participants into placebo and target groups will be done by permuted block randomization. In this way, the size of block is considered 6 and all possible scenarios will be written for the two intervention and control groups, and this will be repeated until the number reaches 72. The method of concealing the allocation is to use a non-transparent sealed envelope in which each of the random entries created is recorded on a card and the cards are arranged inside the envelopes. At the beginning of the registration of participants, based on the order of entry of eligible participants to study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description

All participants in this study are unaware about their grouping because the appearance of the target and placebo are quite similar. Participants are not referred based on their group to clinical follow-up and outcome evaluator and he/she is also unaware of the separation of individuals. The principle investigators are not directly connected with the participants, so they are not aware of their grouping. An importer of data will also be outside the study system, which is generally unaware of the nature of the study.

Placebo

Used

Assignment

Parallel

Other design features

It should be noted that dietary intake and physical activity will be recorded in the study to investigate the confounding factors.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.SUMS.REC.1399.1329

Health conditions studied

1

Description of health condition studied

Sarcopenia

ICD-10 code

M62.84

ICD-10 code description

Sarcopenia

Primary outcomes

1

Description

Hand grip Strength

Timepoint

Baseline and End-of-trial
Method of measurement
Hydraulic Hand Dynamometer

2

Description

Lean body mass

Timepoint

Baseline and End-of-trial

Method of measurement

Dual energy X-ray Absorptiometry (DXA)

Secondary outcomes

1

Description

Appendicular Skeletal Muscle Mass

Timepoint

Baseline and End-of-trial

Method of measurement

Dual energy X-ray Absorptiometry (DXA)

2

Description

weight

Timepoint

Baseline and End-of-trial

Method of measurement

Standardized methods

3

Description

BMI

Timepoint

Baseline and End-of-trial

Method of measurement

Standardized methods

4

Description

Waist circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Standardized methods

5

Description

Calf circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Standardized methods

6

Description

Arm circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Standardized methods

7

Description

Fat mass

Timepoint

Baseline and End-of-trial

Method of measurement

Dual energy X-ray Absorptiometry (DXA)

8

Description

Gynoid fat mass

Timepoint

Baseline and End-of-trial

Method of measurement

Dual energy X-ray Absorptiometry (DXA)

9

Description

Android fat mass

Timepoint

Baseline and End-of-trial

Method of measurement

Dual energy X-ray Absorptiometry (DXA)

10

Description

Physical performance

Timepoint

Baseline and End-of-trial

Method of measurement

The Short Physical Performance Battery (SPPB) score

11

Description

Quality of life

Timepoint

Baseline and End-of-trial

Method of measurement

The Short Form Health Survey-36 (SF-36) questionnaire
and sarcopenia specific quality of life questionnaire
(SarQoL®-IR)

12

Description

percent of fat

Timepoint

Baseline and End-of-trial

Method of measurement

Dual energy X-ray Absorptiometry (DXA)

13

Description

Fasting Blood Sugar (FBS) level

Timepoint

Baseline and End-of-trial

Method of measurement

Auto analyser

14

Description

Lipid profile (LDL, HDL, Triglyceride, total cholesterol)

Timepoint

Baseline and End-of-trial

Method of measurement

Chemical method (kit)

Intervention groups

1

Description

Intervention group: Receiving egg white protein (Gol Powder Golestan Co, Iran) and zinc (Zahravi Pharm Co, Iran)-enriched synbiotic (Pardis Roshd Mehregan Co, Iran) powder daily for 8 weeks

Category

Rehabilitation

2

Description

Control group: Receiving Placebo powder (Pardis Roshd Mehregan Co, Iran) daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hassan Comprehensive Health Center

Full name of responsible person

Dr. Majid Esmailzadeh

Street address

South Fajr Ave., Valfajr Town., Amirkabir Blvd.

City

Shiraz

Province

Fars

Postal code

7176917375

Phone

+98 71 3822 3628

Email

enghelab@sums.ac.ir

2

Recruitment center

Name of recruitment center

Fatemeh Al-zahra Comprehensive Health Center

Full name of responsible person

Dr. Reza Mohammadi

Street address

South Hemmat Ave., Moallem Square

City

Shiraz

Province

Fars

Postal code

7189513544

Phone

+98 71 3632 1909

Email

enghelab@sums.ac.ir

3

Recruitment center

Name of recruitment center

Imam Reza Comprehensive Health Center

Full name of responsible person

Dr. Leyla Bagheri

Street address

next to AL-ahmad School, Koshan Ave.

City

shiraz

Province

Fars

Postal code

7185785844

Phone

+98 71 3822 9226

Email

dr.bagheri2015@gmail.com

4

Recruitment center

Name of recruitment center

Razii Health Center

Full name of responsible person

Ali Zare

Street address

Pashme-shishe Ave, at the entrance to Ahmadabad Town

City

Shiraz

Province

Fars

Postal code

7176967167

Phone

+98 71 3842 8161

Email

info@ darmangahrizi.ir

5

Recruitment center

Name of recruitment center

Mohammad Rasolallah Health center

Full name of responsible person

Maryam Hadadiyan

Street address

Station 4, Pasdaran Ave (Zerehi)

City

Shiraz

Province

Fars

Postal code

7185765595

Phone

+98 71 3822 3050

Email

mri.clinic@gmail.com

6**Recruitment center****Name of recruitment center**

Eghbal Health Center

Full name of responsible person

Dr. Ali Mohammad Kavosh

Street address

Passargad Square, Passargad Blvd

City

Shiraz

Province

Fars

Postal code

7178856834

Phone

+98 71 3834 1251

Email

amkavoush@yahoo.com

7**Recruitment center****Name of recruitment center**

Rezvan Health Center

Full name of responsible person

Dr. Asghar Tavakol

Street address

next to Elahie Shopping Center., Shahid Motahari Blvd

City

Shiraz

Province

Fars

Postal code

7176767396

Phone

+98 71 3844 0301

Email

info@rezvan-clinic.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Office of Research and Technology, Seventh Floor,
Central Building of Shiraz University of Medical
Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

713451978

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Dabbaghmanesh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrine and Metabolic

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Email

dabbaghmanesh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Najmeh Hejazi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition and Food Science,
Fatholmobin alley, Razi blvd

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1007

Email

Najmehhejazi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Mahmoodi

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition and Food Science,
Fatholmobin alley, Razi blvd

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1007

Email

marzieh.mahmoodi123@gmail.com

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