Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Iran (Islamic Republic of)

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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

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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
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2

Recruitment center
Name of recruitment center
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3

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Name of recruitment center
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4

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5

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
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
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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