

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Determination the effect of calcium and vitamin B12 co-supplementation on some anthropometric indices, blood glucose, lipid profile and blood pressure in Individuals with metabolic syndrome: a randomized triple-blind controlled clinical trial

Protocol summary

Study aim

Determination the effect of calcium and vitamin B12 co-supplementation on some anthropometric indices, blood glucose, lipid profile and blood pressure in Individuals with metabolic syndrome

Design

This study is a randomized, triple-blinded, phase 3 controlled clinical trial with 2 parallel groups (intervention and control groups). 56 individuals (28 in each group) were randomized into groups with balanced-blocked randomization.

Settings and conduct

Patients will be selected from clinics and health centers in the city of Shiraz, if desired. Participants will be given educational pamphlets and dietary recommendations to standardize their eating behaviors and prevent drastic and sudden changes in their diet. After a two-week run-in period to standardize dietary behaviors, these individuals will be randomly assigned to two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Individuals with metabolic syndrome Aged 18 to 65 years according to ATPIII Not suffering from kidney, liver, chronic diseases, malignancies, and systemic diseases Not supplementation of calcium, vitamin B12, chromium, magnesium, and vitamin D for the past 3 months before the study. Exclusion criteria: Pregnancy and lactation

Intervention groups

Intervention group: 28 participants will consume Calcium (500 mg CaCO₃) and vitamin B12 (500 mic gr cyanocobalamin) daily with 2 main meals for 8 weeks
Control group : 28 participants will consume Placebo(2 capsules of similar supplements)daily with 2 main meals for 8 weeks

Main outcome variables

Blood glucose, serum insulin , HOMA-IR index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230416057916N1**

Registration date: **2023-11-20, 1402/08/29**

Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**

Update count: **0**

Registration date

2023-11-20, 1402/08/29

Registrant information

Name

seyedeh parastoo pasban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5287 1589

Email address

parastoo_pasban@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-02, 1402/09/11

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination the effect of calcium and vitamin B12 co-supplementation on some anthropometric indices, blood glucose, lipid profile and blood pressure in Individuals with metabolic syndrome: a randomized triple-blind controlled clinical trial

Public title

Determination the effect of calcium and vitamin B12 co-supplementation on some anthropometric indices, blood glucose, lipid profile and blood pressure in Individuals with metabolic syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with metabolic syndrome according to ATP III criteria who tend to participate in research Age range of 18-65 years old. Not suffering from kidney, liver, chronic diseases, malignancies, and systemic diseases. Not supplementation of calcium, vitamin B12, chromium, magnesium, and vitamin D for the past 3 months before the study.

Exclusion criteria:

pregnant and lactating women

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will perform using the random block method (1: 1 ratio) for 2 groups (intervention and control groups). In this method, blocks of two with rotation will be created by an out-of-study person. Then, a block will be randomly selected to determine the groups assigned to the first two participants. The random-blocks selection process will be repeated to determine the random allocation for the entire sample size. For allocation concealment, after determining the random sequence, these sequences will be placed in numbered sealed opaqued envelopes for each participant. An out-of-study person familiar with randomization will perform this process. During the study, by entering any participant in the study, based on the sequence, an envelope will be opened and the allocated group will be revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After determining the random allocation sequence, groups are named A and B based on the assigned names A and B in order and according to the sequence specified in the packets by the person outside the study. Then, based on the assigned blocks, supplements are provided to the participants. Participants are unaware of their assignment to the supplement or placebo group. After collecting the data, the results of the outcomes are analyzed based on groups A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Schools of Health and Nutrition-Shiraz University of Medical Sciences

Street address

Razi Blvd, School of Health and Nutrition

City

Shiraz

Province

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Postal code

14336 - 71348

Approval date

2023-08-06, 1402/05/15

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1402.076

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Serum insulin

Timepoint

At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)

Method of measurement

Enzyme-linked immuno_sorbent assay (ELISA) kit

2

Description

blood glucose

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

Calorimetric Laboratory

3

Description

HOMA-IR index

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

$(\text{Glucose} \times \text{insulin})/405$

Secondary outcomes

1

Description

Body Weight

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

scale

2

Description

body mass index

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

By calculating using the formula with using height and weight

3

Description

waist circumference

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

stadiometer

4

Description

Systolic blood pressure

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

Digital sphygmomanometer

5

Description

diastolic blood pressure

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

Digital sphygmomanometer

6

Description

total cholesterol

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

colorimetric method

7

Description

triglyceride

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

colorimetric method

8

Description

LDL (low-density lipoprotein)

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

colorimetric method

9

Description

HDL (high-density lipoprotein)

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

colorimetric method

Intervention groups

1

Description

Intervention group: In this group, individuals will receive 500 mg of calcium carbonate supplement and 500 mcg of cyanocobalamin (vitamin B12) daily with two main meals for 8 weeks. The calcium supplement is made using calcium carbonate powder and the B12 supplement is made using cyanocobalamin powder at the School of Pharmacy, Shiraz University of Medical Sciences.

Category

Treatment - Other

2**Description**

Control group: In the control group, individuals receive two capsules containing 500 mg of placebo (starch) with the same characteristics in terms of shape, smell, color, etc., along with two main meals every day for 8 weeks.

Category

Placebo

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

Emam REZA clinic

Full name of responsible person

Afsane Ahmadi

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

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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

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

Seyedeh parastoo Pasban

Position

Student

Latest degree

Bachelor

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Afsaneh Ahmadi

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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Phone**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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available