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 $CaCO_3$) 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
Fars

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
(Glucose ×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 cholestrol
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
Street address
Namazi square, Emam REZA Clinic
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Postal code
۱۴۷۳۴-۷۱۳۴۸
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Email
motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Zand street, Shiraz university of medical science
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Email
Sohrabi@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
Seyedeh parastoo Pasban
Position
Student
Latest degree
Bachelor
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Person responsible for updating data

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parastoo_pasban@yahoo.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
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