

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of the Effects of Calcium, Vitamin D, and Calcium plus Vitamin D On Anthropometric Indices, Body Composition, Lipid Profile, Blood Pressure, and Blood Glucose in Overweight or Obese Premenopausal women.

Protocol summary

Summary

We aim to compare the Effects of calcium, vitamin D, and calcium plus vitamin D, as adjuvants to 500 kcal/day energy reduction, on anthropometric indices, body composition, lipid profile, blood glucose, and blood pressure in overweight or obese premenopausal women in a single-center, randomized, double-blind, placebo-controlled, multi-arm, parallel group trial. A total of 100 premenopausal overweight or obese women aged 20-50 will be assigned in a 1:1:1:1 fashion to 4 groups, using blocked randomization. The treatment groups will take 2 tablet of calcium (each containing 500 mg calcium carbonate) or vitamin D (each containing 200 IU vitamin D) alone or 2 tablet of calcium plus vitamin D (each containing 500 mg calcium carbonate and 200 IU vitamin D) and the control group will take 2 tablet of placebo per day for 8 weeks. All groups will be advised not to change their physical activity during the study. Primary outcomes (body mass index, waist circumference, body fat mass, lipid profile, blood glucose, and blood pressure) will be evaluated at baseline and endpoint of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021116555N1**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Hamide Rajaie

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

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rajaieh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-05-15, 1393/02/25

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Calcium, Vitamin D, and Calcium plus Vitamin D On Anthropometric Indices, Body Composition, Lipid Profile, Blood Pressure, and Blood Glucose in Overweight or Obese Premenopausal women.

Public title

Comparison of the Effects of Calcium, Vitamin D, and Calcium plus Vitamin D On Anthropometric Indices, Body Composition, Lipid Profile, Blood Pressure, and Blood Glucose in Overweight or Obese Premenopausal women.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: premenopausal women; age between 20-50 years; BMI between 25-40 kg/m²; not having any cancer or severe endocrine, mental, hepatic, renal, gastrointestinal, cardiovascular, neurologic, rheumatologic, hematologic, skeletal, and eating disorders; not taking any medication, nutritional supplements, or herbal preparations that could affect calcium and vitamin D status, anthropometric indices, body composition, lipid profile, blood pressure, and blood glucose during the last 12 weeks; not having any history of drug intolerance or adverse reaction to the study supplements; Dairy product consumption of ≤ 3 serving /d; consumption of ≤ 5 cups of coffee/d; not being pregnant or lactating; not being a smoker or taking alcohol; not being a participant in other trials over the last 6 months; Stable body weight (body weight change ≤ 3 kg for 3mo before intervention); providing written informed consent. exclusion criteria: development of serious adverse events during the study period and lack of adherence to the study protocol.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz, Zand Street, Olumpezeski Department, The 7th Floor

City

shiraz

Postal code**Approval date**

2013-12-29, 1392/10/08

Ethics committee reference number

92-6836

Health conditions studied**1****Description of health condition studied**

overweight and obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Waist circumference

Timepoint

At the beginning and at the end of the intervention

Method of measurement

Tape measure

2**Description**

body mass index

Timepoint

At the beginning and at the end of the study

Method of measurement

BMI will be calculated as weight (kg)/ height (m)²

3**Description**

Body fat mass

Timepoint

At the beginning and at the end of the intervention

Method of measurement

Bioelectric impedance analyzer

4**Description**

lipid profile

Timepoint

At the beginning and at the end of the intervention

Method of measurement

By use of bt 1500 set and pars test kit

5**Description**

Blood pressure

Timepoint

At the beginning and at the end of the intervention

Method of measurement

mmHg-piezometer

6

Description

blood glucose

Timepoint

At the beginning and at the end of the study

Method of measurement

by Autoanalyzer method using Pars test kit

Secondary outcomes

empty

Intervention groups

1

Description

2 tablet of placebo with low calorie diet

Category

Placebo

2

Description

2 tablet of calcium (500 mg calcium carbonate /tablet) with low calorie diet

Category

Treatment - Drugs

3

Description

2 tablet of calcium plus vitamin D (500 mg calcium carbonate and 200 IU vitamin D / tablet) with low calorie diet

Category

Treatment - Drugs

4

Description

2 tablet of vitamin D (200 IU vitamin D / tablet) with low calorie diet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emem Reza Clinic

Full name of responsible person

Hamide Rajaie

Street address

Shiraz, Namazi square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Hatam

Street address

Zand Street, Olumpezeski Department, The 7th Floor

City

Shiraz

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nutrition and Food Sciences

Full name of responsible person

Hamide Rajaie

Position

MSc candidate of Nutrition

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty