Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 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
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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, Olumpezeshki 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 beginnig and at the end f the intervention
Method of measurement
mmHg-piezometer

6

Description
blood glucose
Timepoint
At the beginnig and at the end f 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, Olumpezeshki 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
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Person responsible for updating data

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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