

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

##### Email address

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/m<sup>2</sup>; 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 <sup>3</sup> 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)<sup>2</sup>

**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**

##### **Street address**

Razi blvd, in front of Bargh stadium

##### **City**

Shiraz

##### **Postal code**

##### **Phone**

+98 71 1725 1001

##### **Fax**

##### **Email**

hamiderajaie@yahoo.com

##### **Web page address**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Hamide Rajaie

**Position**

MSc candidate of nutrition

**Other areas of specialty/work**

**Street address**

Razi blvd, in front of Bargh stadium, School of Nutrition and Food sciences

**City**

Shiraz

**Postal code**

**Phone**

+98 71 1725 1001

**Fax**

**Email**

hamiderajaie@yahoo.com

**Web page address**

**Person responsible for updating data**

**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**

**Street address**

Razi blvd, in front of Bargh stadium

**City**

Shiraz

**Postal code**

**Phone**

00

**Fax**

**Email**

**Web page address**

**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*