# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of VitaminD on Metabolic Profile in Overweight or Obese Womens.

## Protocol summary

**Summary**

Main Objective of this study was assessment of effect of vitamin D supplementation on metabolic profile in the overweight or obese women. In this clinical trial Healthy and overweight or obese women (n=80) with 18-45 years old who referred to clinics of Iran University of Medical Sciences were randomly assigned as a double blind manner into one of following groups based on BMI and age. The intervention group received vitamin D supplement 1 tablet/day (1000 IU vitamin D/tablet) and control group received placebo (lactose) for 12 weeks. 24h dietary recall and food frequency questionnaire, international physical activity questionnaire, anthropometric indices and blood pressures, serum lipid and lipoprotein profile, Apo A-1, Apo B-100, 25(OH)D, calcium and Phosphorus, parathyroid hormone, leptin, insulin, Fasting glucose, and 2-h Post-load serum glucose after 75-oral glucose tolerate test were determined at the baseline and after 12 weeks (90 days).

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138809092709N2**
Registration date: **2010-02-06, 1388/11/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2010-02-06, 1388/11/17

**Registrant information**

**Name**
Farzad Shidfar
**Name of organization / entity**
Iran University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 8862 2755
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**Recruitment status**

**Recruitment complete**

**Funding source**

Iran University of Medical Sciences, Research Institute for Endocrine Sciences of Shaheed Beheshti University of Medical Sciences

**Expected recruitment start date**

2009-11-21, 1388/08/30

**Expected recruitment end date**

2010-01-05, 1388/10/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of VitaminD on Metabolic Profile in Overweight or Obese Womens.

**Public title**

Effect of VitaminD on Metabolic Profile in Overweight or Obese Womens.

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Age of 18–45 years (before menopause), Body Mass Index≥25 (BMI; in kg/m2 calculated as weight in kilograms divided by the square of the height in meters), No Use of Dietary Supplements, Absence of Menopause, Stable Body Weight (body weight change ≥3 kg) for 2 mo before intervention, Good general Health, No Smoking, Normal Blood Pressure Values (≤160/95mm Hg), Cholesterol Concentrations not Requiring Pharmaceutical Treatment, Normal Thyroid Function, No use of Medication that could affect body

weight, No participation in another clinical trial within 6 mo of screening, No breastfeeding or pregnancy. Exclusion criteria: History of Osteoporosis, Rheumatic Disease, Diabetes Mellitus, Epilepsy, Renal Disease under Hemodialysis, Liver disease, Gastrointestinal Disease, Myocardial infarction, Angina Pectoris, Heart Valve Disease, or Pacemaker Implantation. Compliance less than 70 out of 90 prescribed tablets

**Age**
From **18 years** old to **50 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**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**
Ethic Committee School of Health, Iran University of Medical Sciences

**Street address**
Arjantin Square, Alvand Street, School of Health, Iran University of Medical Sciences

**City**
Tehran

**Postal code**
1516846514

**Approval date**
2009-03-14, 1387/12/24

**Ethics committee reference number**
327/5پ26/د

## Health conditions studied

### 1

**Description of health condition studied**
Overweight or Obese

**ICD-10 code**
E66.0

**ICD-10 code description**
Obesity due to excess calories

## Primary outcomes

### 1

**Description**
Overweight or Obese

**Timepoint**
Every Month for 3 months

**Method of measurement**
Anthropometric Index, Bioelectric Impedance

## Secondary outcomes

### 1

**Description**
Insulin Resistance

**Timepoint**
3 months

**Method of measurement**
75-OGTT

### 2

**Description**
Hyperlipidemia

**Timepoint**
3 months

**Method of measurement**
serum lipid levels

### 3

**Description**
Hypertension

**Timepoint**
Every Month for 3 months

**Method of measurement**
Measurement of Blood Pressure

## Intervention groups

### 1

**Description**
Control group: 25 mcg Lactose for 90 days

**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: 1000 IU Vitamin D for 90 days

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Iran University of Medical Sciences

**Full name of responsible person**
Dr.Farzad Shidfar

**Street address**
School of Medicine, Crossroads of Shahid Hemmat and Shahid Chamran Expressways,

**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Mohsen Asadi Lari

**Street address**
School of Medicine, Crossroads of Shahid Hemmat and Shahid Chamran Expressways

**City**
Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Iran 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**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Dr.Farzad Shidfar

**Position**
PhD of Nutrition

**Other areas of specialty/work**

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1449614525

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shidfar44@iums.ac.irfarzadshidfar@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

## 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*