Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 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
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Iran (Islamic Republic of)
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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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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