

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of vitamin D supplementation on anthropometric indices and lipid profile among overweight and obese women : A Placebo-controlled Randomized Clinical trial

#### Protocol summary

##### Summary

This randomized, double blind, placebo- controlled clinical trial study will be carried out to determine the effect of vitamin D supplementation on anthropometric indices and lipid profiles among women aged 18-70 with BMI>25. Seventy-six persons will be randomly assigned in two groups: Intervention group ( receive 2000 IU vitamin D/d) and control group ( receive placebo) that will be surveyed for 3 months. The patients and the medical personnel are not aware of the type of capsules in the boxes (Vitamin D or placebo). Only the researcher is aware of the code written on the boxes of the capsules; so, this study is a double-blind clinical trial. Anthropometric indices including height ( only initially), weight, waist circumference, hip circumference, and lipid profiles, serum calcium and phosphorus, 25-OHD3, and parathyroid hormone will be measured initially and at the end of study. BMI and W/H ratio will be calculated. Energy and Nutrients intake will be assessed by using of a food dietary 24-recall questionnaire for 3 days and N4 software. Data will be analyzed using suitable statistical tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013072814195N1**  
Registration date: **2013-09-05, 1392/06/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-09-05, 1392/06/14

##### Registrant information

##### Name

Ebrahim Falahi

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 1620 0155

##### Email address

falahi.e@lums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor of research and technology of Lorestan University Of Medical Sciences

##### Expected recruitment start date

2013-08-23, 1392/06/01

##### Expected recruitment end date

2013-10-23, 1392/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of vitamin D supplementation on anthropometric indices and lipid profile among overweight and obese women : A Placebo-controlled Randomized Clinical trial

##### Public title

Vitamin D supplementation and obesity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age of 18-70 and BMI>25 Exclusion criteria: to have history of vitamin D deficiency, diabetes

mellitus, thyroid disorders, hyperlipidemia, cardiac diseases and use of vitamins and mineral supplements.

#### Age

From **18 years** old to **70 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **76**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

patients will be randomly assigned into case and control groups.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

##### Street address

Vice chancellor for research and technology, Lorestan University of Medical Sciences, Kamalvand Street, Khoramabad, Lorestan, Iran

##### City

Khoram abad

##### Postal code

#### Approval date

2013-06-01, 1392/03/11

#### Ethics committee reference number

200/86338

## Health conditions studied

### 1

#### Description of health condition studied

obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

### 2

#### Description of health condition studied

overweight

#### ICD-10 code

E66.9

#### ICD-10 code description

Obesity, unspecified

## Primary outcomes

### 1

#### Description

Body Mass Index (BMI)

#### Timepoint

before intervention and 3 months after study

#### Method of measurement

balance-meter

### 2

#### Description

Waist to Hip ratio (W/H)

#### Timepoint

before intervention and 3 months after study

#### Method of measurement

meter

## Secondary outcomes

### 1

#### Description

Total cholesterol

#### Timepoint

before intervention and 3 months after study

#### Method of measurement

spectrophotometer

### 2

#### Description

Triglyceride

#### Timepoint

before intervention and 3 months after study

#### Method of measurement

spectrophotometer

### 3

#### Description

Low density lipoprotein ( LDL)

#### Timepoint

Before intervention and 3 months after study

#### Method of measurement

Spectrophotometer

### 4

#### Description

High density lipoprotein (HDL)

#### Timepoint

before intervention and 3 months after study  
**Method of measurement**  
spectrophotometer

## 5

**Description**  
serum 25 hydroxyvitamin D  
**Timepoint**  
Before intervention and 3 months after study  
**Method of measurement**  
IBL company laboratory kit

## 6

**Description**  
serum calcium  
**Timepoint**  
Before intervention and 3 months after study  
**Method of measurement**  
Spectrophotometer

## 7

**Description**  
serum phosphorus  
**Timepoint**  
Before intervention and 3 months after study  
**Method of measurement**  
spectrophotometer

## 8

**Description**  
Parathyroid hormone (PTH)  
**Timepoint**  
Before intervention and 3 months after study  
**Method of measurement**  
ELISA

## 9

**Description**  
Received energy  
**Timepoint**  
3 days during the intervention  
**Method of measurement**  
Questionnaire and N4 software

## 10

**Description**  
Received calcium  
**Timepoint**  
3 days during the intervention  
**Method of measurement**  
Questionnaire and N4 software

## 11

**Description**  
received phosphorus  
**Timepoint**  
3 days during the intervention

**Method of measurement**  
Questionnaire and N4 software

## 12

**Description**  
Received vitamin D  
**Timepoint**  
3 days during the intervention  
**Method of measurement**  
Questionnaire and N4 software

## 13

**Description**  
Received nutrient elements  
**Timepoint**  
3 days during the intervention  
**Method of measurement**  
Questionnaire and N4 software

## **Intervention groups**

### 1

**Description**  
Patients in the control group receive oral placebo which are specifically designed to have no real effect. They are made of lactose. These pearls in terms of size, shape, packaging and name are exactly similar to the vitamin D pearls. Only the code written on the boxes are different from each other. Frequency and duration of using placebo pearls in the control group are absolutely the same as vitamin D pearls in the intervention group. One pearl will be given to the patients every 25 days until 4 doses. The pearls will be prepared from Daana Pharma Company.

**Category**  
Treatment - Drugs

### 2

**Description**  
Oral vitamin D supplement ( pearl ) 2000 IU/ d ( = 50 µg/d as cholecalciferol ) will be given to the intervention group until 3 months. Each pearl contains 50000 IU vitamin D3. One pearl will be given to the patients every 25 days until 4 doses. The pearls will be prepared from Daana Pharma Company.

**Category**  
Treatment - Drugs

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Ebrahim Falahi 's nutrition clinic  
**Full name of responsible person**  
Ebrahim Falahi  
**Street address**

Ebrahim Falahi 's nutrition clinic, Sepanta  
construction, Shohada Street, Khoramabad, Lorestan,  
Iran

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+98 66 1331 0771

**Fax**  
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kayedi@lums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research Lorestan University of  
Medical Sciences

**Full name of responsible person**  
Mohammad Hasan Kayedi

**Street address**  
Vice chancellor for research Lorestan University of  
Medical Sciences, Kamalvand Street, Khoramabad,  
Lorestan, Iran

**City**  
Khoramabad

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research Lorestan 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**  
Vice chancellor for research and technology of  
Lorestan University Of Medical Sciences

**Full name of responsible person**  
Mohammad Hasan Kayedi

**Position**  
Research and technology vicar of Lorestan University  
of Medical Sciences

#### Other areas of specialty/work

**Street address**  
Vice chancellor for research and technology, Lorestan  
University of Medical Sciences, Kamalvand Street,  
Khoramabad, Lorestan, Iran

**City**  
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**Phone**

## Person responsible for scientific inquiries

#### Contact

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**Position**  
Nutrition phd/ associate

#### Other areas of specialty/work

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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
**Full name of responsible person**

Mina Kheradmand

**Position**  
Medical student

#### Other areas of specialty/work

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mina\_kh2007o@yahoo.com

**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*