

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of Vitamin D supplementation on serum DHEA, Insulin, apo B100, apo A1, PON1 and FFA in obese and overweight people undergoing low calorie diet

#### Protocol summary

##### Summary

Objective: The main objective of this study is to assess the effects of Vitamin D supplementation on changes in the secretion of some hormones such as DHEA and Insulin and antioxidant enzyme to reduce oxidative stress in the body in an overweight and obese adult undergoing of low calorie diet. Design of study: Randomized, double blind, placebo controlled, single center and phase 2-3 trial. Setting and conduct: 70 overweight or obese volunteer age between 20 -50 years old and BMI between 25 – 40 kg/m<sup>2</sup> will be recruited. We have 2 groups: 35 persons that will receive vitamin D , 35 persons that will receive placebo of vitamin D . The duration of intervention is 8 weeks. Participants including major eligibility criteria: Overweight and obese adults 20 -50 years old with BMI between 20 - 40 Kg/m<sup>2</sup>, having a weight loss diet for 3 months before the study initiation and consumption of Vitamin D, use of tanning bed and antioxidant supplementation during and 3 months before study and Vitamin D >30 ng/dl will be excluded participants from study. Intervention: We will start intervention with a bolus dose (50000 IU vit D) in first week along with weight reduction diet and will be followed by daily doses(2000 IU vit D/ day) after a week in intervention group, and control group will receive placebo of vitamin D (edible paraffin) with weight reduction diet for 2 months. Main outcome measures: DHEA, Insulin, apo B100, apo A1, PON 1, FFA will measure with ELIZA. With BIA method we will measure the fat percent of the body and Viscan devices will be used for observation of visceral adipose tissue changes. (after and before of study).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201609102709N38**

Registration date: **2016-10-09, 1395/07/18**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-10-09, 1395/07/18

##### Registrant information

###### Name

Farzad Shidfar

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8862 2755

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Research center for prevention of cardiovascular disease

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Vitamin D supplementation on serum DHEA,

Insulin, apo B100, apo A1, PON1 and FFA in obese and overweight people undergoing low calorie diet

### Public title

Effect of Vitamin D supplementation on regulation of hormones secreted, Anti Oxidant Enzyme and Apo lipoproteins in obese and overweight people undergoing low calorie diet

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: age of 20-50; BMI= 25-40; don't taking the glucose and lipid- lowering drugs; vitamin D deficiency; interesting in participation in research; without any metabolic disease; CHD; diabetes; without autoimmune disease; cancer; without infection disease in research; no smoking; no alcoholism; without immune system suppressor drugs 6 mounts before research; no menstrual bleeding; without any diet 3 mounts before research; no consumption vit D and antioxidant supplementation and multivitamin mineral during research; without use of medication affecting Vitamin D metabolism; without use of tanning bed during the study and 3 months before study initiation; without renal and hepatic diseases; women without polycystic ovary syndrome exclusion criteria: metabolic; CHD; autoimmune disease and cancer; infection disease in research; smoking; alcoholism; use of immune system suppressor drugs 6 mounts before research; menstrual bleeding; diet 3 mounts before research; consumption vit D supplementation and multivitamin mineral during research; use of medication affecting Vitamin D metabolism; use of tanning bed during the study and 3 months before study initiation; Having renal and hepatic diseases; women with polycystic ovary syndrome; no interesting for participation

### Age

From **20 years** old to **50 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **70**

### 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

Ethics Committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Hemmat expressway

##### City

Tehran

##### Postal code

##### Approval date

2016-09-14, 1395/06/24

##### Ethics committee reference number

IR.IUMS.REC.1395.28907

## Health conditions studied

### 1

#### Description of health condition studied

Obesity And Overweight

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

PON 1, FFA

#### Timepoint

Before and after intervention

#### Method of measurement

ELIZA

### 2

#### Description

apo B100, apo A1

#### Timepoint

Before and after intervention

#### Method of measurement

ELIZA

### 3

#### Description

DHEA, Insulin

#### Timepoint

Before and after intervention

#### Method of measurement

ELIZA

## 4

### **Description**

vitamin D

### **Timepoint**

Before and after intervention

### **Method of measurement**

ELIZA

## 5

### **Description**

Fat Percent

### **Timepoint**

Before and after intervention

### **Method of measurement**

BIA method

## 6

### **Description**

BMI

### **Timepoint**

Before and after intervention

### **Method of measurement**

Formula

## 7

### **Description**

Waist circumference

### **Timepoint**

Before and after intervention

### **Method of measurement**

Meter

## 8

### **Description**

Systolic blood pressure

### **Timepoint**

Before and after intervention

### **Method of measurement**

manometer

## 9

### **Description**

Diastolic blood pressure

### **Timepoint**

Before and after intervention

### **Method of measurement**

manometer

## 10

### **Description**

Nutritional status

### **Timepoint**

Before and after intervention

### **Method of measurement**

Measurement of energy and nutrients intake using 24-hour dietary recall method and anthropometric measurement using scale and stadiometer

## 11

### **Description**

Exposure of sunlight

### **Timepoint**

Before and after intervention

### **Method of measurement**

Exposure of sunlight questionnaire

## 12

### **Description**

Physical Activity

### **Timepoint**

Before and after intervention

### **Method of measurement**

International physical activity questionnaire (IPAQ)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention groups: receive 50000 IU vit D once in first week as a blues and 2000 IU vit D per day from second week and 0.5 to 1 kg per week weight lose for 8 weeks in obese and over weight people undergoing low callorie diet. .

#### **Category**

Prevention

### 2

#### **Description**

control group: receive placebo of vitamin D (edible paraffin) every week for 8 weeks in obese and over weight people undergoing low callorie diet.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Iran University of Medical Science

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

Cheshmazar

##### **Street address**

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

##### **City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Javad Moosavi, Assistant of Research and Technology , Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

**City**

Tehran

**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, 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****Name of organization / entity**

Iran University of Medical Sciences, School of Public Health

**Full name of responsible person**

Dr Farzad Shidfar

**Position**

Professor

**Other areas of specialty/work****Street address**

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Elhameh Cheshmazar

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**City**

Tehran

**Postal code****Phone**

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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*