

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/m² 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/m², 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)

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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 bolus and 2000 IU vit D per day from second week and 0.5 to 1 kg per week weight loss for 8 weeks in obese and overweight people undergoing low calorie diet. .

Category

Prevention

2

Description

control group: receive placebo of vitamin D (edible paraffin) every week for 8 weeks in obese and overweight people undergoing low calorie 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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Person responsible for updating data

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Full name of responsible person

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Position

MS.c student in Nutrition Science

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

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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