Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Summary

Objective: The main objective of this study is to assess the effects of Vitamin D spplementation on changes in the secrtion 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 calloeie diet. Design of study: Randomized, double blind, placebo controlled, single center and phase 2-3 trial. Setting and codduct: 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 supplemention 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
shidfar.f@iums.ac.ir

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 overwight 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 sinlights questionnaire

12

Description
Phisical Activity
Timepoint
Before and after intervention
Method of measurement
International phisical activity questionnair (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
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
Postal code
Phone
+98 21 8670 4711
Fax
Email
shidfar.f@iums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Farzad Shidfar
Position
Professor
Other areas of specialty/work
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
Postal code
Phone
+98 21 8670 4711
Fax
Email
shidfar.f@iums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Elhameh Cheshmazar
Position
MS.c student in Nutrition Science
Other areas of specialty/work
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
Postal code
Phone
00
Fax
Email
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