

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Vitamin D supplementation and low calorie diet on serum Omentin ,Spexin , sICAM-1 , hs -CRP and lipid profiles in obese and overweight people

Protocol summary

Summary

Objective: The main objective of this study is to assess the effects of Vitamin D supplementation and low calorie diet on changes in adiposity and regulation of adipokines secreted by adipose tissue to reduce inflammation in the body in an overweight and obese adult population.

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 with weight reduction diet, 35 persons that will receive placebo of vitamin D with weight reduction diet. 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 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: Omentin, Spexin, s ICAM-1 will measure with ELIZA. With BIA method we will measure the fat percent of the body and Visceral 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: **IRCT2015090223861N2**

Registration date: **2015-10-05, 1394/07/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-05, 1394/07/13

Registrant information

Name

Mitra Zarrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4814

Email address

zarrati.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Science, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin D supplementation and low calorie diet on serum Omentin ,Spexin , sICAM-1 , hs -CRP and lipid profiles in obese and overweight people

Public title

Effect of Vitamin D supplementation and low calorie diet on regulation of hormones secreted by adipose tissue and lipid profiles in obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 20-50; BMI= 25-40; don't taking the glucose and lipid- lowering drugs; 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 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: **75**

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

1449614535

Approval date

2015-08-04, 1394/05/13

Ethics committee reference number

26191

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

Waist circumference

Timepoint

Before and after intervention

Method of measurement

meter

2

Description

Omentin, Spexin, sICAM-1

Timepoint

Before and after intervention

Method of measurement

ELIZA

3

Description

Fat percent

Timepoint

Before and after intervention

Method of measurement

BIA method

4

Description

BMI

Timepoint

Before and after intervention

Method of measurement

Formula

5

Description

Vitamin D

Timepoint

Before and after intervention

Method of measurement

ELIZA

6

Description

FBS, HDL-C

Timepoint

Before and after intervention

Method of measurement

Enzymatic Method

7

Description

Triglyceride, Total cholesterol

Timepoint

Before and after intervention

Method of measurement

Photometric

8

Description

LDL-C

Timepoint

Before and after intervention

Method of measurement

Enzymatic Method

9

Description

hs-CRP

Timepoint

Before and after intervention

Method of measurement

Enzymatic Method

10

Description

Diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

manometer

11

Description

Exposure of sunlight

Timepoint

Before and after intervention

Method of measurement

questionnaire

12

Description

Systolic blood pressure

Timepoint

Before and after intervention

Method of measurement

manometer

13

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

14

Description

Physical Activity

Timepoint

Before and after intervention

Method of measurement

questionnaire

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 along with low calorie diet that which reduce the weight 0.5 to 1 kg every week for 8 weeks.

Category

Prevention

2

Description

control group: receive placebo of vitamin D (edible paraffin) with low calorie diet that which reduce the weight 0.5 to 1 kg every week for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

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 Mitra Zarrati

Position

Assistant 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

1449614535

Phone

+98 21 8670 4814

Fax**Email**

zarrati.m@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 Mitra Zarrati

Position

Assistant 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 4814

Fax**Email**

zarrati.m@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

cheshmazar.elham@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