Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 spplementation 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 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 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-1will 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: **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

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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 overwight 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
Phisical 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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Elhameh Cheshmazar

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MS.c student in Nutrition Science

Other areas of specialty/work

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00

Fax

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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