

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effects of vitamin D supplementation on sirtuin-1, Angiogenesis factors and Matrix metalloproteinases enzymes in Obese subjects with Vitamin D Insufficiency/ Deficiency

Protocol summary

Summary

This randomized double blind placebo controlled trial design with aim to determine the Effects of vitamin D supplementation on sirtuin-1, Angiogenesis factors and Matrix metalloproteinases enzymes in Obese subjects with Vitamin D Insufficiency/ Deficiency. According to inclusion and exclusion criteria, 44 Obese subjects with Vitamin D Insufficiency/ Deficiency, age between 18 -60 years old and BMI between 30 - 40 kg/m² will be recruited to the study . Informed written consent form and personality questionnaire will be filled for all of the patients. Participants will be randomly divided into 2 intervention and placebo groups. Subjects in Intervention and Placebo group will receive a bolus dose vitamin D (50000 IU vitamin D weekly) or placebo of vitamin D (edible paraffin) respectively for 12 weeks. Subjects in two group will receive a weight reduction diet for 12 week. For all of the participants anthropometric measurements evaluated on baseline and again after the intervention. Furthermore, 3 dietary records and physical activity record will be filled at baseline and at the end of weeks 6 and 12. biochemical measurements at first and end of the study will be repeated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608223320N13**
Registration date: **2016-11-03, 1395/08/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-03, 1395/08/13

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Nutrition Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D supplementation on sirtuin-1, Angiogenesis factors and Matrix metalloproteinases enzymes in Obese subjects with Vitamin D Insufficiency/ Deficiency

Public title

Effect of vitamin D on obesity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 18-60; BMI= 30-40 Kg/m²; Serum Vitamin D < 50 nmol/L and interesting in participation in research. Exclusion criteria: Alcohol consumption; smoking; pregnant; lactating; menopausal women; very active subjects or athletes; diet 3 months before research ; Glucose and lipid lowering Drugs ; antihypertensive medication; consumption vit D supplementation and multivitamin mineral during research; use of medication affecting Vitamin D metabolism; subjects suffering from metabolic disease ;cardiovascular diseases;renal diseases ; nephrolithiasis; liver diseases; thyroid disease; autoimmune disease; cancer.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

The Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Faculty of Nutrition and food science, Attarneyshabouri street, Golgasht street.

City

Tabriz

Postal code

Iran

Approval date

2016-10-16, 1395/07/25

Ethics committee reference number

IR.TBZMED.REC.1395.761

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Inflammatory factors (MCP-1, IL-1 beta)

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA Kit

2

Description

serum Angiogenesis factors

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA Kit

3

Description

matrix metalloproteinases (MMP-2, MMP-9)

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA Kit

4

Description

Sirtuin-1 (Sirt-1)

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA Kit

5

Description

Toll like receptor-4 (TLR-4)

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Serum level of Vitamin D, calcium, Phosphorus and PTH hormon

Timepoint

Beginning and end of intervention

Method of measurement

Vitamin D and PTH by using ELISA, calcium and Phosphorus by using spectrophotometry

2

Description

Fasting Blood Sugar (F.B.S.)

Timepoint

Beginning and end of intervention

Method of measurement

Enzymatic method

3

Description

Lipid profile (TC,LDL-c, HDL-c, TG)

Timepoint

Beginning and end of intervention

Method of measurement

Triglyceride, total cholesterol and HDL-cholesterol with enzymatic colorimetric and LDL-cholesterol with Friedewald equation

4

Description

Serum insulin level and Insulin resistance

Timepoint

Beginning and end of intervention

Method of measurement

insulin by using Elisa and Insulin resistance by Calculation of HOMA-IR

5

Description

Anthropometric measurements

Timepoint

Beginning and end of intervention

Method of measurement

Weight and Height by using Seca scale and stadiometer respectively, waist to hip ratio will be calculated waist circumference divided to hip circumferences, Body mass index (BMI) will be calculated as weight in kilograms divided by the square of height in meters, fat mass and visceral fat mass by using body Analyser

6

Description

Energy , macro and micro nutrients intake

Timepoint

Baseline, 6 weeks and end of the intervention

Method of measurement

3 day Dietary record questionair

7

Description

Physical activity level

Timepoint

Baseline, 6 weeks and end of the intervention

Method of measurement

International physical activity questionnaire

Intervention groups

1

Description

Intervention groups: receive 50000 IU vit D as blues along with low calorie diet for 12 weeks

Category

Prevention

2

Description

Control group: receive placebo of vitamin D (edible paraffin) with low calorie diet for 12 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykholrais clinic

Full name of responsible person

Dr. Mehrangiz Ebrahimi Mamagani

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutrition Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Faculty of Nutrition and food science, Attarneyshabouri street, Goltasht street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nutrition Research Center, Tabriz 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

Faculty of Nutrition and food science, Tabriz
University of Medical Sciences

Full name of responsible person

Soodabeh Aliashrafi

Position

Ph.D. candidate in Nutrition

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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