Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effects of vitamin D supplementation on sirtuin-1, Angiogenesis factors and Matrix metalloproteinases enzmes 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 enzmes 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
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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 Scienses

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 enzmes 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 subjectes or athletes; diet 3 mounts 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
Begining 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
Begining and end of intervention
Method of measurement
Enzymatic method

3

Description
Lipid profile (TC,LDL-c, HDL-c, TG)
Timepoint
Begining and end of intervention
Method of measurement
Triglyceride, total cholesterol and HDL-cholesterol with enzymatic colorometric and LDL-cholesterol with Friedewald equation

4

Description
Serum insulin level and Insulin resistance
Timepoint
Begining and end of intervention
Method of measurement
insulin by using Elisa and Insulin resistance by Calculation of HOMA-IR

5

Description
Anthropometric measurements
Timepoint
Begining 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 circumferenceas, 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 questionnair

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 Scienses
Full name of responsible person
Dr. Alireza Ostadrahimi
Street address
Faculty of Nutrition and food science, Attarneyshabouri street, Golgasht 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

Scienses

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 Scienses

Full name of responsible person
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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