Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vitamin D supplementation on the metabolomic profiles related to obesity in metabolically healthy vs. metabolically unhealthy obese individuals

Protocol summary

Summary

Objectives: To assess the molecular effect of vitamin D supplementation separately in Metabolically Healthy Obese (MHO) and Metabolically Unhealthy Obese (MUHO). Design: Participants are assessed on the basis of Karelis criteria (according to the rate of their triglycerides, HDL-C, LDL-C, insulin sensitivity, and C reactive protein) and divided into MHO (n=75), MUHO (n=75) and Normal-Weight Metabolically Healthy (NWMH) (n=75) groups. In the phase one, MHO and MUHO are compared to NWMH, with respect to the main outcome of the study in a case-control design. In the phase two, the two obese types are randomly assigned to treatment and placebo groups in a double blind design. Setting: Main outcome measures are assessed in the phase one, in the above three groups of the study and in the phase two in MHO and MUHO. Participants: Participants aged 20-48 years, with BMI ≥ 30 kg/m2, and 18.5 ≤ BMI <25 kg/m2 , not taking supplements and not suffering from non-communicable diseases will be invited to participate in the present study. Intervention: In the phase two, subjects are requested to take one pill (4000 IU vitamin D supplementation or placebo) daily with one of their meals for four months. Compliance monitoring is performed by means of every two-week phone contact and every month clinic visit when calendars showing treatment consumption during the previous month and unused pills are collected and the pills for the next month consumption are distributed among the patients. Main outcome measures: The metabolomic, biochemical, dietary intake and physical activity assessments

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061522762N1**

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

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-05, 1394/07/13

Registrant information

Name

Minoo Bagheri

Name of organization / entity

School of Nutritional Sciences and Dietetic, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Non-communicable Disorders Research Center of Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences

Expected recruitment start date

2015-10-03, 1394/07/11

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of vitamin D supplementation on the metabolomic profiles related to obesity in metabolically healthy vs. metabolically unhealthy obese individuals

Public title
Metabolic Health of obese individuals with the help of vitamin D
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients' consent for participation in the study; Age: of 20-48 years; BMI: of ≥30 and 18.5-24.9 kg/m2 Exclusion criteria: Having weight loss more than 5 kg during three months before the enrollment in the study; following weight loss diets; Pregnancy, lactation and menopause status; Having evidence of non-communicable diseases; Smoking and alcohol consumption
Age
From **20 years** old to **48 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
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
Tehran University of Medical Sciences
Street address
Keshavarz Blvd, Qods St., Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2015-09-20, 1394/06/29
Ethics committee reference number
IR.TUMS.REC.1394.792

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66.9
ICD-10 code description
Simple obesity NOS

Primary outcomes

1

Description
Metabolites
Timepoint
Before and after the intervention
Method of measurement
Liquid Chromatography/ Mass Spectrometry

Secondary outcomes

1

Description
Biochemical factors including Fasting blood glucose and lipids
Timepoint
Before and after the intervention
Method of measurement
Autoanalyzer

2

Description
Anthropometric measures and blood pressure
Timepoint
Before and after the intervention
Method of measurement
digital scale, wall-mounted tape, manometer

Intervention groups

1

Description
Vitamin D 4000 IU one pill per day for four months
Category
Treatment - Drugs

2

Description
Placebo tablet for vitamin D, one pill per day for four months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes and Metabolic Diseases Clinic
Full name of responsible person
Minoo Bagheri
Street address
No 44, Hojjat-dost Alley, Naderi St., Keshavarz Blvd
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Non-communicable Disorders Research Center of Endocrinology and Metabolism Research Institute, Tehra
Full name of responsible person
Dr. Farshad Farzadfar
Street address
Enghelab St., Ostad Nejatoallahi St., Diabetes and Metabolism Clinic 2
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Non-communicable Disorders Research Center of Endocrinology and Metabolism Research Institute, Tehra
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Abolghassem Djazayery
Street address
Keshavarz Blvd, Qods St, Tehran University of Medical Sciences
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
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
Tehran University of Medical Sciences
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Minoo Bagheri
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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