

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 $18.5 \leq$ 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

Mino0 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 Nejatollahi 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 Djazayeri

Street address

Keshavarz Blvd, Qods St, Tehran University of Medical
Sciences

City

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

Full name of responsible person

Mino0 Bagheri

Position

PhD Candidate

Other areas of specialty/work**Street address**

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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