

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of the Vitamin D Supplementation in Obese and Non-Diabetic Individuals; a Double Blind Randomized Clinical Trial.

Protocol summary

Study aim

The aim of this study is to determine the effect of vitamin D supplementation on insulin homeostasis including insulin resistancy and β -cell function in healthy overweight and obese adults.

Design

This is a double-blind, parallel-group, placebo-controlled randomized clinical trial with 70 participants in single center in Tehran. In order to randomized the participants in to groups, we will use coin tossing.

Settings and conduct

This study is performed among patients who will refer from specialized outpatient clinics of Imam Hossein hospital. During the sampling, all of the clients who meet the study criteria are referred to participate in the study. Participants, investigators and outcome assessors are blind in this study.

Participants/Inclusion and exclusion criteria

This study is performed among patients who referred from specialized outpatient clinics of Imam Hossein hospital. During the sampling, all of the clients who meet the study criteria are referred to participate in the study. The inclusion criteria for participants are as follows: 1) age between 18 and 65 years; 2) Body Mass Index (BMI) ≥ 25 kg/m²; 3) serum level of vitamin D < 30 mg/dl.

Intervention groups

The intervention group will receive 50000 IU pearl of vitamin D per week for eight weeks, whereas placebo group will receive placebo instead of vitamin D with same dosage and time.

Main outcome variables

The serum level of fasting blood sugar (FBS), fasting insulin, 1,25 OH vitamin D₃, triglyceride (TG), cholesterol (CHL), high-density lipoprotein (HDL) and low-density lipoprotein (LDL), , Homeostasis Model Assessment 2 (HOMA2) for insulin resistance (HOMA2-IR), β -cell function (HOMA2- β) and insulin sensitivity (HOMA2-S)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200713048089N1**

Registration date: **2020-07-15, 1399/04/25**

Registration timing: **prospective**

Last update: **2020-07-15, 1399/04/25**

Update count: **0**

Registration date

2020-07-15, 1399/04/25

Registrant information

Name

Seyed Shayan Ebadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

seyedshayan.ebadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the Vitamin D Supplementation in Obese and Non-Diabetic Individuals; a Double Blind Randomized Clinical Trial.		Used
Public title	Vitamin D supplementation and insulin homeostasis among healthy overweight and obese adults.	Assignment Parallel
Purpose	Treatment	Other design features
Inclusion/Exclusion criteria		Secondary Ids empty
Inclusion criteria:	Age between 18 and 65 years Body Mass Index (BMI) $\geq$ 25 kg/m ² Serum level of vitamin D < 30 mg/dl	Ethics committees
Exclusion criteria:	Any history of diabetes mellitus, thyroid disorders, gastrointestinal disorders, chronic inflammatory diseases, malignancy, kidney stones, cardiovascular events Taking of drugs which have effects on calcium and phosphorus hemostasis including corticosteroids, thyroxine, warfarin, bisphosphonates, thiazides and vitamin D pregnant or lactating women are not allowed to participate in the study	1
Age	From 18 years old to 65 years old	Ethics committee
Gender	Both	Name of ethics committee Ethics committee of Shahid Beheshti University of Medical Sciences
Phase	N/A	Street address 7th floor, Bldg No.2. Arabi Ave, Velenjak, Tehran
Groups that have been masked	• Participant • Investigator • Outcome assessor • Data analyser	City Tehran
Sample size	Target sample size: 70	Province Tehran
Randomization (investigator's opinion)	Randomized	Postal code 19839-63113
Randomization description	Randomization method: Simple randomization; Random unit: Individual; Randomization tool: Coin tossing Eligible participants are blindly divided, in a parallel manner (1:1), into two equal groups via simple randomization. For the randomization the groups are named as vitamin D and placebo groups. In order to randomize, no individual is superior to another. Then, the sequence of groups is drawn up by coin tossing. In this method, a random number will be assigned to each participant. Then by coin tossing each number (individual) will be assigned to study groups alternately.	Approval date 2017-07-11, 1396/04/20
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number IR.SBMU.MSP.REC.1396.229
Blinding description	The participants are blind to the treatment (vitamin D or placebo) that they will take. Also, the investigators are blind to the type of treatment which any participant receives. But care providers which are responsible for health of individuals are not blind to the treatment and if any contraindication or problem occurs, they will take suitable actions. Furthermore, outcome assessors and data analyzers are blind to the type of treatments.	Health conditions studied
Placebo		1
		Description of health condition studied Diabetes mellitus, Vitamin D deficiency
		ICD-10 code E08
		ICD-10 code description Diabetes mellitus due to underlying condition
		Primary outcomes
		1
		Description Serum level of vitamin D
		Timepoint Before intervention and 8 weeks after intervention
		Method of measurement Serum level of vitamin D will measure using HPLC method with Aglient device.
		2
		Description Fasting insulin
		Timepoint Before intervention and 8 weeks after intervention
		Method of measurement Serum level of fasting insulin will measure using ELISA method with Monobind laboratory kit.

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Description

Homeostasis Model Assessment 2 for insulin resistance

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

I of Homeostasis Model assessment will measure using HOMA2 calculator (www.dtu.ox.ac.uk/homacalculator)

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Description

Homeostasis Model Assessment 2 for β -cell function

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

I of Homeostasis Model assessment will measure using HOMA2 calculator (www.dtu.ox.ac.uk/homacalculator)

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Description

Homeostasis Model Assessment 2 for insulin sensitivity

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

I of Homeostasis Model assessment will measure using HOMA2 calculator (www.dtu.ox.ac.uk/homacalculator)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants in vitamin D group will receive a 50000 IU pearl of vitamin D per week for 8 weeks. The participants are recommended to not change their overall routine physical activity and diet within the study. The compliance for treatment, probable complications and medication side effects are regularly followed via telephone contacts.

Category

Treatment - Drugs

2

Description

Control group: Placebo group will receive a pearl of placebo instead of vitamin D per week for eight weeks. The placebo is similar to the study medication in shape, color, size and taste. The participants are recommended to not change their overall routine physical activity and diet within the study. The compliance for treatment, probable complications and medication side effects are regularly followed via telephone contacts.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Seyed Alireza Ebadi

Street address

Shahid Madani Street, Nezam-Abad, Tehran

City

Tehran

Province

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1617763141

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

5th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Alireza Ebadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Seyed Alireza Ebadi

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All of the data and documents will be published via an article after the end of the study. It should be considered that all of the identity of participants will remain confidential among researchers and no personal information will be revealed.

When the data will become available and for how long

After end of the study. About 3 months after sampling

To whom data/document is available

All of the researchers, scientists and students

Under which criteria data/document could be used

All of the data should be used for further investigations. All of the researchers, scientists and students can send their request.

From where data/document is obtainable

sa.ebadi@sbmu.ac.ir

What processes are involved for a request to access data/document

After sending the identification documents the documents will be sent less than 2 weeks.

Comments