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)

Phone

+98 21 7797 6409

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.

Public title
Vitamin D supplementation and insulin homeostasis among healthy overweight and obese adults.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Body Mass Index (BMI) ≥ 25 kg/m2 Serum level of vitamin D < 30 mg/dl
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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
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.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
7th floor, Bldg No.2. Arabi Ave, Velenjak, Tehran
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2017-07-11, 1396/04/20
Ethics committee reference number
IR.SBMU.MSP.REC.1396.229

Health conditions studied

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.

3

Description
Homeostasis Model Assessment 2 for insulin resistance
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
l of Homeostasis Model assessment will measure using HOMA2 calculator (www.dtu.ox.ac.uk/homacalculator)

4

Description
Homeostasis Model Assessment 2 for β-cell function
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
l of Homeostasis Model assessment will measure using HOMA2 calculator (www.dtu.ox.ac.uk/homacalculator)

5

Description
Homeostasis Model Assessment 2 for insulin sensitivity
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
l 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
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1617763141
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info@ehmc.ir

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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Postal code
1985717443
Phone
+98 21 2243 9781
Email
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

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Person responsible for updating data

Contact

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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 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 use 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 send less than 2 weeks.

Comments