Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D supplementation in overweight and obese people with type 2 diabetes and lipid disorders, and vitamin D deficiency

Protocol summary

Summary

To examine the effect of vitamin D supplementation on type 2 diabetic patients with prior diagnosis of D hypovitaminosis, this randomized placebo controlled clinical trial is desigened. Participants would be randomized into two groups (recieving 50000 IU vitamin D or placebo) for eight weeks. Biochemical and anthropometric indices would be assessd before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707252480N8**
Registration date: **2017-10-13, 1396/07/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-13, 1396/07/21

Registrant information

Name

Mohammad Hassan Eftekhari

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1725 1001

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eftekharim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

No funding.

Expected recruitment start date

2017-01-10, 1395/10/21

Expected recruitment end date

2017-07-10, 1396/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation in overweight and obese people with type 2 diabetes and lipid disorders, and vitamin D deficiency

Public title

Vitamin D supplementation in dibetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for entering the study: Willingness to participate; Prior diagnosis of type 2 diabetes by a specialist; Minimum duration of 2 years diagnosis; No Smoking or Drug abuse; No weight changes over the past 6 months (based on self report); The fixed type and dose of medications used in the last 6 months; Not having severe heart disease, stroke, liver disease, kidney, gastrointestinal, thyroid and parathyroid, rheumatoid arthritis and infectious diseases; Not using any supplements whether containing vitamin D and calcium or anti-oxidant supplements in the last 6 months; Absence of pregnancy or lactation Exit criteria: Misdiagnosis of demographic or anthropometric information; Failure to follow the design of the study (consuming less than 90% of supplements or not taking supplements for more than three consecutive periods); Unusual biochemical specimen; Use of any supplements other than the supplement provided in the study; Use of Venostat (orlistat)

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: **60**

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

Ethics committee of Shiraz University Of Medical Science

Street address

Zand Street, opposite of Palestine Street, The headquarters of Shiraz

City

Shiraz

Postal code

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

ir.sums.rec.1396.22

Health conditions studied

1

Description of health condition studied

Diabetic patients with Vitamin D Defficiency

ICD-10 code

E10.9,E55.

ICD-10 code description

diabetes (mellitus)(nonobese)(obese),Vitamin D deficiency, unspecified

Primary outcomes

1

Description

TG

Timepoint

before and after 8 weeks of intervention

Method of measurement

Standard Enzymatic Method

Secondary outcomes

1

Description

Fbs

Timepoint

before and after 8 weeks of intervention

Method of measurement

Standard Enzymatic Method

2

Description

Serum vitamin D level

Timepoint

before and after 8 weeks of intervention

Method of measurement

Standard Enzymatic Method

3

Description

Net Weight Changes

Timepoint

before and after 8 weeks of intervention

Method of measurement

Scales

4

Description

waist circumference changes

Timepoint

before and after 8 weeks of intervention

Method of measurement

By flexible stata meter (at highest level of circumference)

5

Description

Glycated Hemoglubin

Timepoint

before and after 8 weeks of intervention

Method of measurement

Via standard labratory method (RIA)

6

Description

TG

Timepoint

before and after 8 weeks of intervention

Method of measurement

Standard Enzymatic Method

7

Description
TC
Timepoint
before and after 8 weeks of intervention
Method of measurement
Standard Enzymatic Method

8

Description
LDL
Timepoint
before and after 8 weeks of intervention
Method of measurement
Standard Enzymatic Method

9

Description
HDL
Timepoint
before and after 8 weeks of intervention
Method of measurement
Standard Enzymatic Method

10

Description
MAD
Timepoint
before and after 8 weeks of intervention
Method of measurement
Standard Enzymatic Method

11

Description
hsCRP
Timepoint
before and after 8 weeks of intervention
Method of measurement
ELISA kit

Intervention groups

1

Description
"Intervention group': Vitamin D supplementation(50000 IU/Week)
Category
Treatment - Drugs

2

Description
"Control group": placebo (1 capsule of corn oil same in shape, weight, color, and size with intervention supplement weekly)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Health Care Center
Full name of responsible person
Sahar Shahriari
Street address
Namazi Square
City
Shirazz

2

Recruitment center
Name of recruitment center
Faghihi health care center
Full name of responsible person
Sahar Shahriari
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University Of Medical Science
Full name of responsible person
Dr Seyed Basir Hashemi
Street address
Office Of Research and Technology ,Central Building Shiraz University Of O Medical Science, Street Zand
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University Of Medical Science
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

Departman of Clinical Nutrition, School of Nutrionand Food sciences, Shiraz university of medical Sc

Full name of responsible person

Sahar Shahriari

Position

Master Of Science In Nutrition

Other areas of specialty/work

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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