

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Aug 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 designed. Participants would be randomized into two groups (receiving 50000 IU vitamin D or placebo) for eight weeks. Biochemical and anthropometric indices would be assessed 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

Email address

eftekhari@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 diabetic 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 Hemoglobin

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

Department of Clinical Nutrition, School of Nutrition and Food Sciences, Shiraz University of Medical Sciences

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