

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effect of vitamin D supplementation on flow-mediated dilatation (FMD), Oxidized LDL (oxLDL) and Intracellular adhesion molecule 1 (ICAM1) in type 2 diabetic patients with hypertension.

Protocol summary

Study aim

Comparison of mean serum level of oxLDL, ICAM1 and serum levels of vitamin D in the intervention and placebo groups before and after the intervention. Comparison of blood flow-mediated dilatation in the intervention and placebo groups before and after the intervention.

Design

Double-blind, parallel groups, placebo - controlled randomized clinical trial

Settings and conduct

Hypertensive diabetic patients treated in the endocrinology clinic of Imam Khomeini Hospital. 48 of whom consented to participate in the study. At first general information were obtained. Individuals were coded into groups 1 and 2 using the Bias Coin method. Cans containing vitamin D and placebo capsules were coded 2 and 1 by Someone other than the researcher and provided to the researcher. Blood pressure, height, weight and BMI were measured. All patients completed sunlight questionnaire, 24-hour recall and MET physical activity questionnaire. Blood samples were taken to measure serum levels of vitamin D, ICAM1 and oxLDL. Ultrasonographic FMD evaluation was performed on the same day after a 15-minute horizontal rest and standard conditions. The intervention duration was 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 35 to 65 years old; at least 5 years diabetes history; similar and specific drugs. Exclusion criteria: pregnancy and lactation; gastrointestinal diseases; any history of cardiovascular problem; endocrine diseases; malignancy; type 1 diabetes; BMI<4; drugs affecting vitamin D and calcium metabolism; insulin therapy and weight loss medications such as Orlistat.

Intervention groups

The intervention group (n = 23): one daily vitamin D capsule containing 2000 IU of cholecalciferol. The

placebo group (n = 21): placebo capsules containing lactose powder and magnesium stearate.

Main outcome variables

ICAM1; oxLDL; FMD; Vitamin D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045861N1**

Registration date: **2020-01-27, 1398/11/07**

Registration timing: **retrospective**

Last update: **2020-01-27, 1398/11/07**

Update count: **0**

Registration date

2020-01-27, 1398/11/07

Registrant information

Name

Reyhaneh Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3382 0985

Email address

ghasemi.sa@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

2019-02-16, 1397/11/27
Actual recruitment end date
2019-06-17, 1398/03/27
Trial completion date
2019-09-24, 1398/07/02

Scientific title

Effect of vitamin D supplementation on flow-mediated dilatation (FMD), Oxidized LDL (oxLDL) and Intracellular adhesion molecule 1 (ICAM1) in type 2 diabetic patients with hypertension.

Public title

Effect of vitamin D supplementation on type 2 diabetic patients with hypertension.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

At least 5 years diabetes history based on self-reported Diabetes control with metformin, Glibenclamide, glitazone, Gliclazide or a combination of these Blood pressure control with any of the Angiotensin receptor blockers (ARB), ACE Inhibitor, Calcium channel blockers (CCB), Thiazide diuretics or a combination of these

Exclusion criteria:

Pregnancy and lactation Gastrointestinal diseases such as malabsorption History of cardiovascular problems Kidney, liver and other endocrine diseases Malignancy Type 1 diabetes BMI<40 The consumption of vitamin D and multivitamin mineral supplements over the past 3 months Drugs affecting vitamin D and calcium metabolism, Insulin therapy Weight loss medications such as Orlistat

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **46**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals were coded into groups 1 and 2 using the Bias Coin method

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals were coded into groups 1 and 2. Also Cans containing vitamin D and placebo capsules were coded 2 and 1 by someone other than the researcher and provided to the researcher in order to ensure that the researcher was not informed about the type of capsule

consumed by each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Boostan dormitory, Zaker Ave., Apadana, Urmia Town

City

Urmia

Province

West Azarbaijan

Postal code

6257757168

Approval date

2019-01-16, 1397/10/26

Ethics committee reference number

IR.UMSU.REC.1397.404

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Flow-mediated dilatation changes

Timepoint

At baseline and week12

Method of measurement

Ultrasonography

2

Description

ICAM1

Timepoint

At baseline and week 12

Method of measurement

Serum level measurement using ELISA kit

3

Description

Oxidized LDL

Timepoint

At baseline and week 12

Method of measurement

Serum level measurement using ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 vitamin D capsule daily containing 2000 IU of cholecalciferol manufactured by Nanohyat pharmaceutical company, Iran

Category

Treatment - Drugs

2

Description

Control group: 1 capsule daily containing lactose powder and magnesium stearate manufactured by Nanohyat pharmaceutical company, Iran

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ali Akbar Nasiri

Street address

Imam Khomeini Hospital, Ershad Ave., Modarres Blvd., Urmia Town

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5714783734

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+98 44 3223 4897

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nasiriali7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Firooz Ghaderi Pakdel

Street address

Urmia University of medical science, Resalat Blvd., Urmia Town

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Reyhaneh Ghasemi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available