

# 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

**City**

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**Province**

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**Postal code**

5714783734

**Phone**

+98 44 3223 4897

**Email**

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

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

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**Postal code**

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**Phone**

+98 44 3193 7224

**Email**

fgpakdell@yahoo.com

**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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## Person responsible for scientific inquiries

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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