

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation Of the Effectiveness Of Vitamin D Supplementation On Glycemic Control In Type 2 Diabetic Patients With Vitamin D Deficiency

Protocol summary

2015-03-04, 1393/12/13

Summary

1,25 Dihydroxy vit D, increases production and secretion of several hormones, including insulin. The purpose of this study is to evaluate the effect of vitamin D supplementation on glycemic control of type 2 diabetic patients with vitamin D deficiency. Inclusion criteria include: a diagnosis of type 2 diabetes; HbA1c levels between 7-12% and serum vitamin D levels less than 30 ng / ml; Exclusion criteria include: patients with a history of ESRD; every pregnant patient; the patient with a deficiency or inadequate vitamin D; any patient with nephrotic syndrome; history of present hypercalcemia and hyperparathyroidism, sarcoidosis; lung and bone malignancy. Among patients with 35-65 years and type 2 diabetes mellitus referred to Imam Khomeini Hospital of Ardabil, 100 patients randomly will be measured vitamin D levels. Those who have vitamin D deficiency, will be selected for a period of 12 weeks. We selected randomized clinical trial for 3 months. Fasting blood samples for analysis of baseline levels of fasting blood glucose, HbA1c, serum levels of calcium and vitamin D and will be collected. blood pressure will be measured and Patients BMI will be calculated. Patients will be prescribed for 4 weeks, 4 capsules of vitamin D and 2 months, 2 capsules of vitamin D. After 3 months (end of study) values will be measured in these patients again.

Registrant information

Name

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Name of organization / entity

Ardabil University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ardabil University Of Medical Sciences

Expected recruitment start date

2015-02-22, 1393/12/03

Expected recruitment end date

2015-03-08, 1393/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012520788N1**

Registration date: **2015-03-04, 1393/12/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

Evaluation Of the Effectiveness Of Vitamin D Supplementation On Glycemic Control In Type 2 Diabetic Patients With Vitamin D Deficiency

Public title

The Effect Of Vitamin D Supplementation On Glycemic Control In Diabetic Patients With Vitamin D Deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: A Diagnosis Of Type 2 Diabetes; HbA1c

Levels Between 7-12%; Serum Vitamin D Levels Less Than 30 ng / ml Exclusion Criteria: Patients With A History Of ESRD; Every Pregnant Patient; The Patient With A Deficiency Or Inadequate Vitamin D; Any Patient With Nephrotic Syndrome; History Of Present Hypercalcemia And Hyperparathyroidism; Sarcoidosis; Lung And Bone Malignancy.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical University of Ardabil

Street address

Medical University of Ardabil

City

Ardabil

Postal code

5619853141

Approval date

2015-01-18, 1393/10/28

Ethics committee reference number

Arums.REC.93.57.

Health conditions studied**1****Description of health condition studied**

Diabetes Mellitus

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes Mellitus

Primary outcomes**1****Description**

HbA1c

Timepoint

Before intervention, three months after the intervention.

Method of measurement

HPLC

Secondary outcomes**1****Description**

Blood pressure

Timepoint

Before intervention, three months after the intervention.

Method of measurement

Mm-Hg using a mercury sphygmomanometer

Intervention groups**1****Description**

Vitamin D, Capsules 50 mg orally, 4 times a month and 2 times in 2 months after

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Clinic of Emam Khomeini Hospital

Full name of responsible person**Street address****City**

Ardabil

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Medical University of Ardabil

Full name of responsible person

Dr Shahram Habibzadeh

Street address

Medical University of Ardabil

City

Ardabil

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Medical University of Ardabil

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

Medical University of Ardabil

Full name of responsible person

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Web page address

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