

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of vitamin D injection on Endothelial Biomarker, hs-CRP, Lipid profile and Glycemic Control in vitamin D deficient patients with Type 2 Diabetes

Protocol summary

Summary

This study is randomized, control, clinical trial. The aim of this study is to evaluate the effect of vitamin D injection on Endothelial Biomarker, hs-CRP, Lipid profile and Glycemic Control in vitamin D deficient patients with Type 2 Diabetes. Sample of the study includes 50 of Patients (25 patients in the Vitamin D group and 25 patients in the control group). The intervention group receives 200000IU Vitamin D injection at baseline and 4-weeks and one group had no treatment. Anthropometric and biochemical measurements, medical and general information and food records for each person will be collected at the beginning and end of the study. Duration of intervention will be 2 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100336539N1**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-08, 1396/08/17

Registrant information

Name

farhang mirzavandi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences Yazd

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D injection on Endothelial Biomarker, hs-CRP, Lipid profile and Glycemic Control in vitamin D deficient patients with Type 2 Diabetes

Public title

The effect of vitamin D on the treatment of type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: Diabetes mellitus patients and HbA1c hemoglobin less than 9 percent 2-25 levels of hydroxyvitamin D (25 OHD) less than 20 ng / ml 3- Age range 30-60 years and Exclusion criteria: 1 - Lack of interest in participating in the study-2-Use of vitamin D supplementation over the past 3 months-3-Kidney, liver disease, Malabsorption syndrome, Severe infection-4-Use of immunosuppressive drugs-5- Pregnancy and lactation-6- Use of insulin

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences Yazd

Street address

Yazd - Alam Square - Anonymous Martyrs Blvd -
Campus of Shahid Sadoughi University of Medical
Sciences Yazd - Yazd School of Public Hea

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Yazd

Postal code

8915173160

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

IR.SSU.SPH.REC.1396.89

Health conditions studied

1

Description of health condition studied

Type II diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

E-Selectin of serum

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

ELISA method

2

Description

high-sensitivity C-reactive protein (hs-CRP) of serum

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

ELISA method

3

Description

Serum fasting blood sugar(FBS)

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

4

Description

Vitamin D of serum

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

ELISA method

5

Description

Serum total cholesterol

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

6

Description

Serum triglyceride level (TG)

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

7

Description

Serum high density lipoprotein cholesterol (HDL-C)

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

8**Description**

Serum low Density Lipoprotein cholesterol (LDL-C)

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

9**Description**

Serum Calcium

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

10**Description**

serum Phosphorus

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Enzymatic method

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

Weight

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

by body Calibrated scale

2**Description**

Body mass index

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

by body Calibrated scale

3**Description**

Body fat percent

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

by body Calibrated scale

4**Description**

Muscle mass percent

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

by body Calibrated scale

5**Description**

visceral fat percent

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

by body Calibrated scale

6**Description**

evaluation of patients diet

Timepoint

Before the intervention and two months after the start of the study

Method of measurement

Three-day food record

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

Intervention: injection of Vitamin D 400000 IU first and one month after the start of the study each time 200,000 IU Duration of study 2 months. The control group does not receive anything.

Category

Treatment - Drugs

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

Diabetes Research Center, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Fakhredin Shiranian

Street address

Department of Nutrition, Faculty of Public Health, Shahid Sadoughi University of Medical Sciences, Alem Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd

Full name of responsible person

Dr. Hassan Mozaffari Khosravi

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Yazd

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences Yazd

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

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Full name of responsible person

FARHANG MIRZAVANDI

Position

MSc student of Health Sciences in Nutrition

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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