Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Diabeties

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 Diabeties.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 Diabeties

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
City
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
evalution 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 Sadughi University of Medical Sciences, Alem Square
City

Yazd

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

Street address

Yazd- Alam-Blvarchy Square, Anonymous-Campus, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

City

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

Shahid Sadoughi University of Medical Sciences and Health Services Yazd

Full name of responsible person

FARHANG MIRZAVANDI

Position

MSc student of Health Sciences in Nutrition

Other areas of specialty/work

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Position

PhD in Nutrition Sciences

Other areas of specialty/work

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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