

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of vitamin D injection on Endothelial Biomarkers, hs-CRP and blood pressure in vitamin D deficient patients with Type 2 Diabetics

Protocol summary

Study aim

The aim of this study is to evaluate the effect of vitamin D injection on Endothelial Biomarkers, hs-CRP and blood pressure in vitamin D deficient patients with Type 2 Diabetics.

Design

controlled clinical trial with a parallel group

Settings and conduct

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. This study is done at the Yazd Diabetes Center.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes with vitamin D deficiency

Intervention groups

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.

Main outcome variables

Improve vitamin D levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171003036539N2**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

farhang mirzavandi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D injection on Endothelial Biomarkers, hs-CRP and blood pressure in vitamin D deficient patients with Type 2 Diabetics

Public title

The effect of vitamin D supplements on the treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetes mellitus patients and HbA1c hemoglobin less than 9 levels of hydroxyvitamin D (25 OHD) less than 20 ng / ml Age range 30-60 years

Exclusion criteria:

Use of vitamin D supplementation over the past 3 months- Kidney,liver disease,Malabsorption syndrome,Severe infection Pregnancy and lactation Use of insulin

Age

From **30 years** old to **70 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

50people who have been admitted to the study, who had been previously visited by the doctor,using random codes from the computer (random allocation table), participants were classified into two groups (each group number- 25) . Randomization was performed by computer-generated and using random location software. The number 1 through 50 were assigned in the intervention and control groups. The first person was given number one and the last was given number 50.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

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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Province

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Postal code

8915173160

Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.SSU.SPH.REC.1396.173

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

p-selectin of serum

Timepoint

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

Method of measurement

ELISA method

Secondary outcomes

1

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

2

Description

Vitamin D of serum

Timepoint

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

Method of measurement

ELISA method

3

Description

Systolic blood pressure

Timepoint

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

Method of measurement

Mercury barometer

4

Description

Diastolic blood pressure

Timepoint

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

Method of measurement

Mercury barometer

5

Description

wight

Timepoint

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

Method of measurement

scales

6

Description

Serum Calcium

Timepoint

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

Method of measurement

Enzymatic method

7

Description

serum Phosphorus

Timepoint

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

Method of measurement

Enzymatic method

8

Description

Intercellular Adhesion Molecule-1 of serum

Timepoint

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

Method of measurement

ELISA method

9

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

10

Description

Beck Depression score

Timepoint

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

Method of measurement

Beck Depression Inventory2 score

11

Description

Serum fasting blood sugar(FBS)

Timepoint

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

Method of measurement

Enzymatic method

12

Description

Serum triglyceride level (TG)

Timepoint

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

Method of measurement

Enzymatic method

Intervention groups

1

Description

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.

Category

Treatment - Drugs

2

Description

Control group: 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Yazd 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
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Full name of responsible person
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Position
MSc student of Health Sciences in Nutrition
Latest degree
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available