

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of vitamin D injection on tumor necrosis factor alpha (TNF) and vascular cell adhesion molecule 1 (SVCAM-1) in vitamin D deficient patients with Type 2 Diabetes

Protocol summary

Study aim

The aim of this study was to determine the effect of vitamin D injection supplement on tumor necrosis factor-alpha and the soluble form of vascular cell adhesion molecule 1 in patients with type 2 diabetes with vitamin D deficiency.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 1-2 was performed on 50 patients. Random computer-derived random codes (random allocation table) were used for randomization.

Settings and conduct

This study was performed on patients with diabetes, with vitamin D deficiency who refer to the Diabetes Center of Yazd city. The researcher and the patient were blinded. For hiding after randomization by random allocation table, we selected and numbered the sample volume of the envelope and then wrote the control and intervention group identification sheets based on the output of the table and put them in the envelope and then sealed the envelope to allocate medicine or We provided control to the secretary or medical staff.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Diabetic patients and HbA1c less than 9 %. 2-25-hydroxy vitamin d serum level less than 20 ng per ml. 3-Aged 30-60. Exclusion criteria: 1- Lack of interest in participating in study. 2-Use of vitamin D supplements during the last 3 months. 3-Kidney and liver diseases, malabsorption syndrome, severe infection. 4- Use of immunosuppressive drugs. 5-Pregnancy and lactation. 6-Use of insulin.

Intervention groups

The intervention group received an injectable vitamin D supplement at a dose of 400,000 IU in two injections (200,000 IU each time) and the control group did not receive any specific intervention.

Main outcome variables

Determination and comparison of mean serum levels of vitamin D, tumor necrosis factor-alpha and soluble form of vascular cell adhesion molecule -1 between and within the study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200913048697N1**

Registration date: **2020-09-28, 1399/07/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-28, 1399/07/07**

Update count: **0**

Registration date

2020-09-28, 1399/07/07

Registrant information

Name

Siavash Babaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 8778

Email address

s.babaie86@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vitamin D injection on tumor necrosis factor alpha (TNF) and vascular cell adhesion molecule 1 (SVCAM-1) in vitamin D deficient patients with Type 2 Diabetes

Public title
Effect of vitamin d on inflammatory factors

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Having diabetes and HbA1c less than 9 percent 25-hydroxy vitamin d serum level less than 20 ng per milliliter Aged 30-60
Exclusion criteria:
Lack of interest in participating in the study Vitamin d supplement intake in last 3 month Impaired absorption, liver and kidney diseases and severe infection Immune system suppressor medication Pregnancy and lactation Insulin using

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

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The 50 patients included in the study will be divided into intervention group with monthly vitamin D injection (25 subjects) and control group (25 subjects) using simple randomization and SPSS statistical software. Individuals will be randomly assigned to intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
For concealment after randomization by the random allocation table, we select and number the envelope sample size and then write the control and intervention group identification sheets based on the output of the table and then provide the sealed envelope for drug or control allocation for medical staff.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research School of Health - Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Yazd, Alam Square, Shohadaye Gomnam Boulevard, Medical Sciences Campus, Faculty of Health

City

Yazd

Province

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Postal code

۸۹۱۵۱۷۳۱۶۰

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.SSU.SPH.REC.1399.041

Health conditions studied

1

Description of health condition studied

Diabetic patients with vitamin D deficiency.

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Tumor necrosis factor alpha.

Timepoint

before intervention, 2 month after intervention.

Method of measurement

Using laboratory kits for measuring the desired factors with ELISA technique.

2

Description

soluble vascular cell adhesion molecule 1

Timepoint

before intervention, 2 month after intervention.

Method of measurement

Using laboratory kits for measuring the desired factors with ELISA technique.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Doses of 200,000 international units of vitamin D were injected at the beginning and one month after the start of the study, a total of 400,000 international units.

Category

Prevention

2

Description

Control group: The control group does not receive anything.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research and Treatment Center

Full name of responsible person

Dr. Saeed Hossein Khalilzadeh

Street address

The end of Art Hall Alley,,Shahid Sadoughi Blvd ,.
Bahonar Square towards Azadi Square,. Yazd.

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7916978477

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drc@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaie

Street address

University of Medical Science, Central Administration,
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dvc.research@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Yazd university of Medical Science

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Siavash Babaie

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Full name of responsible person

Siavash Babaie

Position

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Bachelor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
anthropometric and inflammatory factors
When the data will become available and for how long
starting 3months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Only for personal verification of the data to confirm the accuracy of the study
From where data/document is obtainable
s.bababie86@gmail.com 0098 9133873046
What processes are involved for a request to access data/document
Only if the applicant is affiliated with university centers can apply by contact number or email.
Comments