Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of vitamin D deficiency treatment on control of blood glucose in type 2 diabetic patients

Protocol summary

Study aim
The effect of vitamin D deficiency on blood glucose control in type II diabetic patients

Design
This study was a double-blind clinical trial with control and control group randomly divided into two groups of 40 with 6 blocks. The first group was treated with vitamin D at 50,000 units per week for 12 weeks. And the second group will receive the placebo in these 12 weeks.

Settings and conduct
This study was done in different countries and cities of Iran. This study was conducted in Kashan and in diabetic patients referring to the clinic of Kashan Beheshti Hospital. In this study all patients are blinded and assured in the end of the study is decided according to their lab tests on how to continue their treatment. A laboratory partner who performs blood sampling also only knows the patients with the name of the researcher. The practitioner will not be advised in the treatment and how to choose patients.

Participants/Inclusion and exclusion criteria
Passed over 2 years after diagnosis of type 2 diabetes. Detection of Type 2 diabetes according to standard criteria HbA1C criteria range from 8-7 Fasting blood sugar is less than 200 Taking oral hypoglycemic drugs The level of vitamin D is between 10-19.9 Desire to cooperate in designing and completing a written questionnaire Lack of severe underlying disease causing a patient's disability or vitamin D metastable.

Intervention groups
This study will be done on 80 patients diagnosed with type 2 diabetes mellitus. Vitamin D levels are measured in patients and patients with vitamin D levels 10-19.9 are selected and randomly divided into six groups of 40 with six blocks, the first group with vitamin D at 50,000 units per week for 12 weeks are treated and the second group will receive the placebo in these 12 weeks.

Main outcome variables
Age؛ Gender؛ Vit D treatment؛ Duration of diabetes؛ ؛ FBS Cr؛ TG CHO ؛ LDL ؛ HDL and HbA1C

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190505043480N1**
Registration date: **2019-06-23, 1398/04/02**
Registration timing: **retrospective**

Last update: **2019-06-23, 1398/04/02**
Update count: **0**

Registration date
2019-06-23, 1398/04/02

Registrant information

Name
Hamed Hajmoradi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5554 0021

Email address
hajmoradi-h@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-13, 1398/02/23

Expected recruitment end date
2019-05-31, 1398/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of vitamin D deficiency treatment on control of blood glucose in type 2 diabetic patients

Public title
Effect of Vitamin D on Blood Glucose Control

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
It's been over 2 years since the diagnosis of type 2 diabetes Detection of Type 2 diabetes according to standard criteria HbA1C criteria range from 8-7 Fasting Blood glucose under 200 Using of oral Glucose-lowering Agents Not taking vitamin D and calcium supplements at least 3 months ago, not taking medications that affect vitamin D metabolism (corticosteroids, calcitonin, cytotoxic drugs and immunosuppressive drugs, anticonvulsants) at least 3 months ago, lack of diseases that affect the metabolism of vitamins D effects (such as liver, endocrine, and cancer) Desire to cooperate in designing and completing a written questionnaire he level of vitamin D is between 10 and 19.9 Age between 30-85

Exclusion criteria:
Malnutrition, Infertility, Oligomenorrhea, Pregnancy, Breastfeeding, Malignancy Smoking, alcohol consumption Immobilization for more than a week Acute and chronic active infections, acute and chronic inflammatory diseases, cardiovascular, liver, kidney, thyroid and parathyroid disorders

Age
From **30 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
This double-blind, randomized clinical trial is conducted on 80 patients diagnosed with type 2 diabetes mellitus and referred to the clinic of Kashan's Shahid Beheshti Hospital in 1398. Eligible patients are selected according to entry and exit criteria and after receiving a complete explanation of the study plan, they will receive written consent. Demographic and anthropometric characteristics of the patients will be recorded according to the individual questionnaire including age, sex, height, weight and duration of diabetes. The level of vitamin D in patients is then measured and patients with vitamin D 10-19.9 will be selected and randomly divided into six groups of 40 with 6 blocks, the first group with vitamin D of 50,000 IU They are treated weekly for 12 weeks, and the second group receives placebo in these 12 weeks.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants are fully relied on how to study, and they are assured that at the end of the 12 weeks, according to the lab tests, they will decide on how to continue their treatment. The clinical practitioners are laboratory personnel who Obtaining samples has been selected and they are only collected through the introduction of a letter with a completely identical text that I am giving it to patients and referring to the laboratory. The data analyst is also a third-party epidemiologist who does not know how to do the work.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethinic committee of kashan University of Medical sciences

Street address
5th of Qotb –e Ravandi Blvd. , Kashan, IRAN

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Kashan

Province
Isfehan

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8115187159

Approval date
2019-05-06, 1398/02/16

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.019

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11.00

ICD-10 code description
Type 2 diabetes mellitus

2

Description of health condition studied
Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

Glycosylated hemoglobin(HbA1c)

Timepoint

Before starting the study and 12 weeks after starting vitamin D

Method of measurement

Laboratory

2

Description

Vitamin D levels

Timepoint

Before starting the study and 12 weeks after starting vitamin D

Method of measurement

Laboratory

Secondary outcomes

1

Description

Changes in level of liver enzymes(AST-ALT-ALK)

Timepoint

Before the study began and 12 weeks later

Method of measurement

laboratory

2

Description

Changes in lipid profiles (LDL-HDL-TG)

Timepoint

Before the study began and 12 weeks later

Method of measurement

laboratory

3

Description

Renal Profile Changes (BUN-Creatinine)

Timepoint

Before the study began and 12 weeks later

Method of measurement

laboratory

Intervention groups

1

Description

Intervention group: In this group patients will be treated by oral 50000 IU vitamin D3 capsule(cholecalciferil), once every week for 12 weeks. The capsule manufacture in Zahravi pharmaceutical co.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients with oral placebo capsules similar to the Vitamin D capsule of 50,000 IU, made by Barij Essens co, packaged in the similare blister package, will be treated for once weekly, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic, Kashan Shahid Beheshti Hospital

Full name of responsible person

Hajmoradi Hamed

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Banafshe

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5th of Qotb –e Ravandi Blvd, Kashan University of Medical sciences, IRAN

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Web page address

http://research.kaums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Hajmoradi Hamed

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

professor

Latest degree

Subspecialist

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Person responsible for updating data

Contact

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Full name of responsible person

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resident

Latest degree

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Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

After reading the data about the study outcomes after unidentifiable individuals are shared.

When the data will become available and for how long

After printing results

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in scientific papers and continuing scientific work in this field

From where data/document is obtainable

Data collection will be possible in coordination with the Department of Science and Research of Kashan University of Medical Sciences.
www.medicine.kaums.ac.ir

What processes are involved for a request to access data/document

At the request of the Department of Science and Research of Kashan University of Medical Sciences

Comments