

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Study of Vitamin D Supplement Effect on Improvement of Glycemic Indexes in Type 2 Diabetics

Protocol summary

Summary

This clinical trial is conducted on 60 patients who are certainly suffering from Type 2 Diabetes Mellitus and referred to Endocrinology Clinic of Shahr-e- Kord University of Medical Sciences. Among Type 2 diabetics referred to this clinic, the patients with one of the exclusion criteria are excluded from the study and the remaining patients are randomly divided into two 30-person groups. First, the level of 25OHD is measured in all patients so that Vitamin D status is specified in Type 2 diabetics in question, and then the first group shall be treated by edible Calcitriol, for 0.5 microgram per day during 12 weeks or Pearl Vitamin D and the second group shall be treated by Placebo during these 12 weeks. Prior to the study, all patients were tested by Fasting Blood Sugar (FBS), 2 hour post prandial glucose, and lipid profile including Total Cholesterol and Triglyceride, LDL-C, HDL-C, HbA1C, and 25OHD tests. After 12 weeks, the testing variables of Fasting Blood Sugar (FBS), 2 hour post prandial glucose, and lipid profile including Total Cholesterol and Triglyceride, LDL-C, HDL-C, HbA1C, and 25OHD tests will be repeated for both groups and both groups are compared with paired t-test. It is tried that all 60 selected patients are approximately placed in similar range in terms of diabetes control, diet and activity level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011185191N6**
Registration date: **2011-10-05, 1390/07/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-05, 1390/07/13

Registrant information

Name

Mohammad Saeed Behradmanesh

Name of organization / entity

Shahr-e-Kord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 4917

Email address

sbehradmanesh@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Cellular Molecular Research Center

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study of Vitamin D Supplement Effect on Improvement of Glycemic Indexes in Type 2 Diabetics

Public title

The Study of Vitamin D Supplement Effect on Improvement of Glycemic Indexes in Type 2 Diabetics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient's consent for participation in the study; Final diagnosis of Type 2 diabetes based on standard criteria; having no advanced nephrology and liver diseases as well as any other chronic diseases

based on patient biography and clinical examination; having 0.7.5% \geq HBA1C \geq 7%. Exclusion criteria: Non-satisfaction of the patient for participation in the study; any chronic debilitative critical diseases based on patient biography and clinical examination; improper diabetes control HBA1C>7.5%; taking any calcium and vitamin D supplement during the last six months.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Shahr-e-Kord University of Medical Sciences

Street address

Ayatollah kashani Blvd, Shahr-e-Kord University of Medical Sciences

City

Shahr-e-kord

Postal code**Approval date**

2010-04-22, 1389/02/02

Ethics committee reference number

89-2-2

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Measure of glycosylated hemoglobin (HbA1c)

Timepoint

3 months

Method of measurement

Laboratory

2**Description**

Fasting glucose levels

Timepoint

3 months

Method of measurement

Laboratory

3**Description**

Glucose levels 2 hours after a meal

Timepoint

3 months

Method of measurement

Laboratory

4**Description**

Total cholesterol and triglyceride levels and LDL-C and HDL-C

Timepoint

3 months

Method of measurement

Laboratory

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

Vitamin D level

Timepoint

3 months

Method of measurement

Laboratory

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

Daily half micrograms of calcitriol for 12 weeks

Category

Treatment - Drugs

2

Description

Placebo for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic

Full name of responsible person

Dr Kamran Roudini

Street address

City

Shahr-e-kord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cellular Molecular Research Center

Full name of responsible person

Ms Beheshteh Amiri

Street address

Ayatollah kashani Blvd

City

Shahr-e-Kord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cellular Molecular Research Center

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

Shahr-e-Kord University of Medical Sciences

Full name of responsible person

Dr Kamran Roudini

Position

Internal Medicine Resident

Other areas of specialty/work

Street address

Ayatollah kashani Blvd, Shahr-e-kord University of Medical Sciences

City

Shahr-e-Kord

Postal code

Phone

+98 38 1222 8262

Fax

Email

Roudini.k@gmail .com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahr-e-Kord University of Medical Sciences

Full name of responsible person

Dr Saeed Behradmanesh

Position

Endocrinologist

Other areas of specialty/work

Street address

Ayatollah kashani Blvd, Shahr-e-kord University of Medical Sciences

City

Shahr-e-kord

Postal code

Phone

+98 381225063

Fax

Email

sbehradmanesh@skums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr Kamran Roudini

Position

Internal Medicine Resident

Other areas of specialty/work

Street address

Ayatollah Kashani Blvd.

City

ShahreKord

Postal code

Phone

Fax

Email

Roudini.k@gmail.com

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