Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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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% ≥ HBA1C ≥ 7%. Exclusion criteria: Non-satisfaction of the patient for participation in the study; any chronic debilitive 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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