Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of calcitriol supplementation on glucose, insulin, hemoglobin A1C, lipid profile and oxidative stress markers in hyperlipidemic patients with type 2 diabetes mellitus, Shiraz, 2009

Protocol summary

Summary

To evaluate the effect of calcitriol supplementation on diabetes control and its complications in hyperlipidemic patients with type 2 diabetes mellitus 70 diabetic patients with age>30 years, Hb.A1C<8%, FBS<160 mg/dl, Serum Calcium < 10.5 mg/dl, LDL<150 mg/dl were recruited from Shahid Motahari clinic in Shiraz, Iran. They were randomly divided into 2 groups based on block randomization protocol: treatment group received 0.5 mcg calcitriol per day and control group received placebo. They were followed for 3 months. At weeks 0, 6 and 12 from the start of the study, fasting blood samples were taken.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806282480N1**
Registration date: **2010-05-08, 1389/02/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-08, 1389/02/18

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2009-08-01, 1388/05/10

Expected recruitment end date

2009-12-31, 1388/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of calcitriol supplementation on glucose, insulin, hemoglobin A1C, lipid profile and oxidative stress markers in hyperlipidemic patients with type 2 diabetes mellitus, Shiraz, 2009

Public title

Evaluation of the effect of calcitriol supplementation on diabetes control and its complications in hyperlipidemic patients with type 2 diabetes mellitus, Shiraz, 2009

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age>30 years, Hb.A1C<8%, FBS<160 mg/dl, Serum Calcium < 10.5 mg/dl, LDL<150 mg/dl, normal liver and kidney function, no history of kidney stone, not taking insulin therapy, no hypercalcemia was seen. Exclusion criteria: using vitamin D supplement, pregnancy, smoking, UVB exposure with therapeutic goals, acute kidney or liver disease, hypercalcemia, hyperparathyroidism.

Age

From **30 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

Approval date

2009-08-03, 1388/05/12

Ethics committee reference number

88-4617

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

FBS

Timepoint

3 times, with 1.5 month intervals

Method of measurement

Auto analyser

2

Description

serum insulin

Timepoint

3 times, with 1.5 month intervals

Method of measurement

with Eliza kit, Monobind

Secondary outcomes

1

Description

Hb.A1C

Timepoint

before and after intervention

Method of measurement

Nycocard kit

2

Description

MDA (Malondialdehyde)

Timepoint

before and after intervention

Method of measurement

spectrophotometery

3

Description

lipid profile

Timepoint

3 times, with 1.5 month intervals

Method of measurement

auto analysor

4

Description

interleukin 1

Timepoint

2 times with 3 month intervals

Method of measurement

eliza kit

5

Description

interleukin 6

Timepoint

2 times with 3 month intervals

Method of measurement

eliza kit

6

Description

interleukin 18

Timepoint
2 times with 3 month intervals
Method of measurement
eliza kit

7

Description
CRP
Timepoint
2 times with 3 month intervals
Method of measurement
eliza kit

Intervention groups

1

Description
calcitriol intake, 0.5 mcg per day, for 3 months
Category
Treatment - Drugs

2

Description
placebo intake for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari clinic
Full name of responsible person
Street address
Shahid Motahari clinic
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz university of medical sciences
Full name of responsible person
Dr. Mohammad Hossein Dabaghmanesh
Street address
Shiraz university of medical sciences
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz university of medical sciences
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
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Full name of responsible person
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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