

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

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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.

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

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

Mohammad Hassan Eftekhari

Name of organization / entity

Shiraz University of Medical Sciences

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Email address

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
spectrophotometry

3

Description
lipid profile

Timepoint
3 times, with 1.5 month intervals

Method of measurement
auto analyser

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**

School of health and nutrition, Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Akbarzadeh

Position

MSc. student of nutrition

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

PHD of nutrition, assistant professor of nutrition department

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

MSc student

Other areas of specialty/work

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Shiraz

Postal code

Phone

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