

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of vitamin D3 on glycemic control, inflammatory markers and 24hr urine protein in patients with insufficiency and deficiency in serum vitamin D level in type 2 diabetes mellitus

Protocol summary

Summary

The purpose of this study is to evaluate the Effect of vitamin D3 on glycemic control & inflammatory markers & 24hr urine protein in patients with insufficiency and deficiency in serum vitamin D level in type 2 diabetes mellitus. Inclusion criteria include: patients with type 2 diabetes treated with insulin or medication to lower blood sugar levels; have a vitamin D deficiency; insulin and blood sugar-lowering drugs are used on a regular basis; during the last month are not taking calcium and vitamin D supplementation; proteinuria more than 200 mg per 24 hours urine; the serum creatinine less than 2 or GFR above 50. Exclusion criteria: type 1 diabetes; the normal level of vitamin D; not cooperating with the regular use of drugs; serum creatinine greater than 2 or GFR less than 50; D Calcium intake during the last month; unwillingness to continue to participate in the study; calcium in phosphorus above 55; calcium greater than 10, all conditions that affect the ESR, except for the lack of vitamin D. Sixty diabetes type II patients examined by serum biomarker measurement (vitamin D level, fasting blood glucose, HbA1C, 24 -hour urine protein, ESR, CRP). The patients with vitamin D deficiency divided to case and control groups. Case group treated by pearl vitamin D 50000 units, and control group by placebo for a two month. In the end of study, the same biomarkers examined again and compared with before treatment measurements in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081723656N1**

Registration date: **2015-08-24, 1394/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-24, 1394/06/02

Registrant information

Name

Mohsen Kabiri Samani

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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kabiri.m@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-07-16, 1393/04/25

Expected recruitment end date

2014-08-16, 1393/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D3 on glycemic control, inflammatory markers and 24hr urine protein in patients with insufficiency and deficiency in serum vitamin D level in type 2 diabetes mellitus

Public title

Effect of vitamin D3 on glycemic control, inflammatory markers and 24hr urine protein in patients with insufficiency and deficiency in serum vitamin D level in type 2 diabetes mellitus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with type 2 diabetes treated with insulin or medication to lower blood sugar levels; have a vitamin D deficiency; insulin and blood sugar-lowering drugs are used on a regular basis; during the last month are not taking calcium and vitamin D supplementation; proteinuria more than 200 mg per 24 hours urine; the serum creatinine less than 2 or GFR above 50. Exclusion criteria: type 1 diabetes; the normal level of vitamin D; not cooperating with the regular use of drugs; serum creatinine greater than 2 or GFR less than 50; D Calcium intake during the last month; unwillingness to continue to participate in the study; calcium in phosphorus above 55; calcium greater than 10, all conditions that affect the ESR, except for the lack of vitamin D.

Age
From **41 years** old to **88 years** old

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)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Rahmatie, Shahrekord
City
Shahrekord
Postal code
Approval date

2014-07-13, 1393/04/22

Ethics committee reference number
92-6-29

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E10, E11,

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
FBS

Timepoint
Before , two and four months after the intervention.

Method of measurement
Lab data

2

Description
Hemoglobin A1c

Timepoint
Before , two and four months after the intervention.

Method of measurement
Lab data

3

Description
ESR

Timepoint
Before , two and four months after the intervention.

Method of measurement
Lab data

4

Description
CRP

Timepoint
Before , two and four months after the intervention.

Method of measurement
Lab data

5

Description
Proteinuria

Timepoint
Before , two and four months after the intervention.

Method of measurement
Lab data

Secondary outcomes

1

Description

Phosphor

Timepoint

Before , two and four months after the intervention.

Method of measurement

Lab data

2

Description

Calcium

Timepoint

Before , two and four months after the intervention.

Method of measurement

Lab data

3

Description

Albumin

Timepoint

Before , two and four months after the intervention.

Method of measurement

Lab data

Intervention groups

1

Description

Intervention group 1: Tablets Pearl vitamin D3 -50000
one unit every week to two months.

Category

Treatment - Drugs

2

Description

Intervention group 2: control group was used placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Imam Ali

Full name of responsible person

Street address

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Ali Momeny

Street address

Shahrekord University of Medical Sciences, Rahmatie,
Shahrekord

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord 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

Associate Professor, School of Medicine

Full name of responsible person

Dr Ali Momeny

Position

Shahrekord University of Medical Sciences

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

Dr Ali Momeny

Position

Associate Professor, School of Medicine

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Fax**Email****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

Person responsible for updating data**Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Mohsen Kabiri Samani

Position**Other areas of specialty/work**