

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of vitamin D3 supplementation on some of metabolic and inflammatory markers in patients with diabetic nephropathy

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

(1) Objectives: The effect of vitamin D3 supplementation on markers of metabolic and inflammatory markers in patients with diabetic nephropathy. (2) Design: Randomized Double blind clinical Trial, with a sample size of 50 patients. (3) Setting and conduct: After the patients participating, were randomly divided into 2 groups. The first blood samples were taken from the subjects after assessing their anthropometric measurements and taking their 3day food record. Then, they were asked to consume either of the Vitamin D3 or placebo for 8 weeks. More so, they were asked not to change their regular diet, activity and medicine during the study. Second Blood samples were also taken after an overnight fasting and before-after analysis was performed finally. (4) including major eligibility criteria: (4-a) Major Inclusion Criteria: With type 2 diabetes, blood glucose less than 140 mg/dl, stage 3 and 4 diabetic nephropathy and albuminuria more than 30 mg/day, the lack of proof for vitamin D is more than 15 ng/l and less than 30 ng/l. (4-b) Major Exclusion Criteria: Calcium and vitamin D supplements during the study, more than 2.5 mg/dL phosphorus, calcium modified more than 10 mg/dl, taking magnesium antacids, thiazide diuretics consumption. (5) Intervention: Group 1 (Intervention group) who weekly received 1 pearl containing 50000 unit cholecalciferol supplements after the lunch meal, and Group 2 (Placebo group) who received placebo as the same, all for 8 weeks. (6) Main outcome measures (Variables): Albuminuria, Fasting blood sugar, Serum insulin, TNF α , Interlukin6, Hemoglobin A1c, Blood pressure

Last update:

Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz university of medical sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511173140N15**

Registration date: **2016-01-17, 1394/10/27**

Scientific title

The effects of vitamin D3 supplementation on some of metabolic and inflammatory markers in patients with diabetic nephropathy

Public title

Effect of vitamin D3 in the treatment of patients with diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 20 to 50 years; have type 2 diabetes; control blood glucose less than 140 mg / dl; With BMI 20-35; stage 3 nad 4 diabetic nephropathy; albuminuria more than 30 mg per day; lack of proven vitamin D levels over 15 ng / l and less than 30 ng / l; Do not use calcium supplements and vitamin D in the last 3 months; Not taking medications that affect vitamin D metabolism, such as parathyroid hormone, estrogen, and calcitonin; willingness to cooperate Exclusion criteria: Changing the dose of the blood glucose lowering drugs; Change of medication or other treatment; taking calcium and vitamin D supplements during the study; with glomerulonephritis; Phosphorus more than 2/5 mg / dl; corrected calcium more than 10 mg / dl; active malignancy; The possibility of requiring renal replacement over the next year; uncontrolled high blood pressure; Taking antacids containing magnesium; Thiazide diuretics consumption; unwillingness to participate or to continue working

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Ethics committee of Tabriz university of medical sciences

Street address

Third floor, Central building No. 2, Tabriz University of Medical Sciences, Golgasht- street Tabriz

City

Tabriz

Postal code**Approval date**

2015-11-09, 1394/08/18

Ethics committee reference number

TBZMED.REC.1394.682

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

diabetic nephropathy

ICD-10 code

E10

ICD-10 code description

With renal complications Diabetic nephropathy

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

Albuminuria

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Measurement of Albumin in urin by using kits

2**Description**

Fasting blood glucose

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Measurement of fasting blood glucose by using kits

3**Description**

Hemoglobin A1c

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Using ion exchange chromatography

4**Description**

Insulin

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Elisa

5**Description**

TNF- α

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Elisa

6

Description

Interlukin6

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Elisa

7

Description

Added at 2016-02-16: Catalase activity

Timepoint

Added at 2016-02-16: Before and after intervention (8 weeks)

Method of measurement

Added at 2016-02-16: AEBI with using a UV/visbile spectrophotometer

Secondary outcomes

1

Description

blood pressure

Timepoint

Before and after intervention (8 weeks)

Method of measurement

pressure indicator

Intervention groups

1

Description

Control group: Receiving 1 placebo containing Miglyol oil weekly for 8 weeks.

Category

Placebo

2

Description

Intervention group: Receiving vitamin D3 supplement which contains 50,000 IU Pearl vitamin D3 cholecalciferol weekly for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital Endocrinology Clinic

Full name of responsible person

Asra Esfandiari

Street address

Daneshgah street, Golgasht street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. AliReza Ostad Rahimi

Street address

Faculty of Nutrition, Attar street ,Golgasht street ,Tabriz

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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