Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

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

Protocol summary

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, TNFα, Interlukin6, Hemoglobin A1c, Blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511173140N15**

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

Registration timing: **registered_while_recruiting**

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

Iran (Islamic Republic of)

Phone

+98 41 1435 7580

Email address

pourghassemb@tbzmed.ac.ir

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

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

City

Tabriz

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

City

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

Faculty of Nutrition,Tabriz University of Medical Sciences,Tabriz

Full name of responsible person

Asra Esfandiari

Position

Health Sciences in nutrition graduate student

Other areas of specialty/work

Street address

Daneshgah street,Tabriz university of Medical sciences Tabriz

City

Tabriz

Postal code

Phone

+98 41 3281 9128

Fax

Email

asra.esfandiari@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Nutrition,Tabriz University of Medical Sciences,Tabriz

Full name of responsible person
Dr,Bahram Pourghassem Gargari

Position
Ph.D. in Nutrition

Other areas of specialty/work

Street address
Daneshgah street,Tabriz university of Medical sciences Tabriz

City
Tabriz

Postal code

Phone
+98 41 3336 2117

Fax

Email
bahrampg@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of Nutrition,Tabriz University of Medical Sciences,Tabriz

Full name of responsible person
Asra Esfandiari

Position
Health Sciences in nutrition graduate student

Other areas of specialty/work

Street address
Tabriz university of Medical sciences, Daneshgah street, Tabriz

City
Tabriz

Postal code

Phone
00

Fax

Email
asra.esfandiari@gmail.com

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