

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vitamin D supplements in diabetic retinopathy in type 2 diabetic patients

Protocol summary

Study aim

Determining the Effect of Vitamin D Supplementation in Diabetic Retinopathy Determine the effect of vitamin D supplements on diabetic retinopathy according to the thickness of the macula Determine the effect of vitamin D supplements on diabetic retinopathy according to age Determine the effect of vitamin D supplements on the incidence of diabetic retinopathy according to sex Determination of the effect of vitamin D supplements on diabetic retinopathy according to HbA1C

Design

Clinical trial with interventional and control group, community-based and pragmatic, with parallel groups, blinded two-way

Settings and conduct

Patients with type 2 diabetes with a minimum age of 35 years are randomized by questioner in two groups by lottery. Two groups of patients receiving vitamin D (50) and a placebo control group (50 people) are divided into two groups. Patients in the target group receive 50,000 vitamin D units once every two weeks and to the placebo control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age of at least 35 years. 2. Patients with type 2 diabetes who are treated with insulin or combined therapy Exclusion criteria 1- The history of any ocular disease (glaucoma, hypertensive retinopathy and cataract), or the history of eye surgery, or previous intra-ocular injections or visual acuity less than 6/10. 2- History of chronic disease such as sarcoidosis, hyperparathyroidism and seizure, bone cancer or lung and liver cirrhosis and ...

Intervention groups

Patients with type 2 diabetes with a minimum age of 35 years are randomized by questioner in two groups by lottery. Patients are divided into two groups of recipients Vitamin 50 (D n) and placebo control group (50 people) are divided. Patients in the target group receive 50,000 vitamin D units once every two weeks and to the placebo

control group.

Main outcome variables

Diabetic retinopathy

General information

Reason for update

Acronym

DRD

IRCT registration information

IRCT registration number: **IRCT20180922041089N1**

Registration date: **2019-01-24, 1397/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-24, 1397/11/04**

Update count: **0**

Registration date

2019-01-24, 1397/11/04

Registrant information

Name

Abolfazl Zendehtdel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5517 6031

Email address

azendedel@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplements in diabetic retinopathy in type 2 diabetic patients

Public title

Study the effect of vitamin D supplements on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of at least 35 years Patients with type 2 diabetes who are treated with insulin or combined therapy (insulin with antidiabetic pill) They have NPDRP without the need for specific ophthalmologic treatment interventions HbA1C levels below 8% Systolic blood pressure up to 130 Diastolic blood pressure is up to 80 mmHg Normal GFR is proportional to age based on MDRD formula The amount of 24-hour urine albumin is less than 300 milligrams.

Exclusion criteria:

The history of any ocular disease (glaucoma, hypertensive retinopathy and cataract), or the history of eye surgery, or previous intra-ocular injections or visual acuity less than 6/10 History of chronic disease such as sarcoidosis, hyperparathyroidism and seizure, bone cancer or lung and liver cirrhosis and... History of bariatric surgery or absorption disorders or any other disease indicating vitamin D intake. History of kidney stones Pregnancy and lactation History of taking phenofibrate, thiazolidinedione, anticonvulsants, or drugs that interfere with the metabolism of vitamin D or produce eye effects, including macular edema. The history of severe psychiatric illnesses such as schizophrenia, mood disorders, borderline disorders. Regular supplementation of D supplementation in the last three months or during the study (in the control group) History of any drug allergy or side effects. Participants are reluctant to take drugs or placebo Participate in another research project over the past 3 months HbA1C levels of 8% and more Glucocorticoid intake in the last 3 months BMI more than 35 The amount of 24-hour urine albumin exceeds 300 milligrams The GFR is greater than the normal range based on the age-appropriate MDRD formula.

Age

From **35 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation role method will be used. There are 30 green cards (interventions) and 30 orange cards (controls) inside white envelopes for women and the same number for men that were placed inside two separate lottery boxes and randomly each eligible patient will be assigned a card according to the sex.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate the bias caused by the patient's or doctor's knowledge of the received treatment type and its possible effect on the outcome of the study, the study is done in two blind ways. Considering that the vitamin D and placebo tablets are placed in the same capsule, the patient and the assessing physician are not aware of the type of received drug.

Placebo

Used

Assignment

Parallel

Other design features

Regarding the high prevalence of diabetes and the consequent increase in the prevalence of diabetic retinopathy in Iran and the growing health problem due to reduced visual acuity and blindness of the population with diabetic retinopathy, which is often active in working age, and preventable blindness due to Referring to the fact that family physicians are the first level of exposure to diabetic patients, if there is a positive result in this study, it is recommended that vitamin D supplements be used in all diabetic patients to prevent the development of diabetic retinopathy.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Ethics Committee for Biomedical Research

Street address

Abuzar St, Ziaian Hospital, Tehran Town

City

Tehran

Province

Tehran

Postal code

1366736511

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.258

Health conditions studied

1

Description of health condition studied

Diabetic retinopathy

ICD-10 code

E08.31

ICD-10 code description

Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy

Primary outcomes

1

Description

diabetic retinopathy

Timepoint

Start studying, 3months later, 6months later

Method of measurement

ETDRS scale

Secondary outcomes

1

Description

body mass index

Timepoint

Start studying, 6 months later

Method of measurement

measurement

2

Description

HA1C test

Timepoint

Start studying, 6 months later

Method of measurement

Laboratory measurement

3

Description

Macular thickness

Timepoint

Start studying, 6 months later

Method of measurement

OCT

Intervention groups

1

Description

Intervention group: Patients with type 2 diabetes who are at least 35 years of age who are referred to an internal clinic or family physician are referred to an ophthalmologist for annual screening for diabetic retinopathy. During a visit, after 3 months of onset of the study, photogramography Digital Retinol is used to diagnose diabetic syringopathy. Patients in the target

group treated with vitamin D were checked for vitamin D monitoring during the third month of their visit. Patients re-enter the specialty internists and ophthalmologists after 6 months of admission. The level of HbA1c marker hyalipid is checked and checked by an ophthalmologist and ophthalmologist, fluorosine angiography and OCT, and digital retinal photogramography for patients Done.

Category

Treatment - Drugs

2

Description

Control group: Patients with type 2 diabetes who are at least 35 years of age who are referred to an internal clinic or family physician are referred to an ophthalmologist for annual screening for diabetic retinopathy. The on-site, placebo-controlled, Once receive. All patients are followed up at the beginning of the study 3 months later and 6 months later by an intern doctor and an ophthalmologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaieian Hospital

Full name of responsible person

Mansour ShaporSamaee

Street address

Abuzar St, Ziaian Hospital, Tehran Town

City

Tehran

Province

Tehran

Postal code

1366736511

Phone

+98 21 5517 6031

Email

s.masamaei@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraeeian

Street address

Keshavarz Blvd - Qods St, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code
1366736511

Phone
+98 21 5517 6130

Email
research-zia@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Grant Proposals

Proportion provided by this source
10

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Abolfazl Zendeheel

Position
Ziaian Hospital Education Assistant

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

Street address
Abuzar Street, Abuzar Square, opposite the 17th district of Ziaeean Hospital

City
Tehran

Province
Tehran

Postal code
1366736511

Phone
+98 21 5517 6031

Fax
+98 21 5575 1333

Email
azendedel@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Abolfazl Zendeheel

Position
Ziaian Hospital Education Assistant

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

Street address
Abuzar Street, Abuzar Square, opposite the 17th district of Ziaeean Hospital

City
Tehran

Province
Tehran

Postal code
1366736511

Phone
+98 21 5517 6031

Fax
+98 21 5575 1333

Email
azendedel@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Nassim Ebadati

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Family Physician

Street address
Abuzar St, Ziaian Hospital, Tehran Town

City
Tehran

Province
Tehran

Postal code
1366736511

Phone
+98 21 5517 6031

Email
nasimebadati@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available