Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Vitamin D on serum levels and gene Expression of Enzymes Allodose Reductase, Glucosamine Transferase and Glutamine Fructose Amidotransferase in Type 2 Diabetes Patients

Protocol summary

Study aim

Determination of serum levels and gene expression of , aldose reductase, hexosamine transferase ,glutamine-fructose amidotransferase at the begining and end of the study

Design

This study was a double blind clinical trial in which two groups of 37 participants participated, both of whom were diabetic patients who had all the criteria for entering the study. The first group received supplements and the second group of homogeneous diabetic patients were BMI for age and sex, who took placebo and were selected as controls. . We used permuted random block method .

Settings and conduct

Stratified randomization was done using computer-generated random numbers. Eligible participants were randomized to receive daily capsules of placebo or vitamin D in a double-blind fashion. All participants who visit Endocrinology and Metabolism Research Institute, after an overnight fast, venous blood samples were taken at the beginning and at the end of the study. During the study both patients and researcher were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 35-65 years; Diabetic patients who take metformin and sulfonylureas and do not take supplemental drugs. with BMI less than 30 kg/m2. Exclusion criteria: Subjects on any anti-inflammatory medication; Patients on insulin therapy; Patients with renal disease; cancer; infectious diseases; pregnant women; Coronary artery disease and vitamin D supplementation

Intervention groups

Accidental assignment to intervention groups (vitamin D and control (medication), double-blinded Parallel

Main outcome variables

Determine the serum levels of glucose, glycosylated hemoglobin and glutamine-fructose amidotransferase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170813035665N2**
Registration date: **2019-06-12, 1398/03/22**
Registration timing: **retrospective**

Last update: **2019-06-12, 1398/03/22**
Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name
Mahnaz Zarei

Name of organization / entity
Tehran University of Medical Siences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

2018-12-06, 1397/09/15

Actual recruitment end date
2019-04-14, 1398/01/25
Trial completion date
2019-04-14, 1398/01/25

Scientific title
Effect of Vitamin D on serum levels and gene Expression of Enzymes Allodose Reductase, Glucosamine Transferase and Glutamine Fructose Amidotransferase in Type 2 Diabetes Patients

Public title
Effect of Vitamin D on Enzymes in type 2 Diabetes patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes who have35-65 years . patients take oral hypoglycemic drugs metformin or sulphonylurea. patients have been diagnosed with at least two years. Patients do not take supplemental drugs. patients with BMI less than 30 kg/m2
Exclusion criteria:
do not use vitamin D ,vitamin B6 supplements or diets at least 4-6 weeks before the intervention.
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Actual sample size reached: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified randomization was done using computer-generated random numbers. Eligible participants were randomized to receive daily tablets of placebo or vitamin D in a double-blind fashion.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the investigator and patients were blinded from the time of randomization until analysis was comleted.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National etics committee of biomedical research
Street address
floor 13, Department A ,Ministry of Health and Medical Education, Simaye Iran Ave Qods Town
City
Tehran
Province
Tehran
Postal code
1354619551
Approval date
2019-03-16, 1397/12/25
Ethics committee reference number
IR.IAU.SRB.REC.1397.168

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
GFAT
Timepoint
Before and three months after intervention
Method of measurement
Elisa

2

Description
Aldose reductase
Timepoint
Before and three months after intervention
Method of measurement
Elisa

3

Description
Hexose amin transferase
Timepoint
Before and three months after intervention
Method of measurement
Elisa

4

Description
Glutamin Amido transferase gene expression
Timepoint
Before and three months after intervention
Method of measurement
Real time PCR

5

Description
Hexose amin transferase gene expression
Timepoint
Before and three months after intervention
Method of measurement
Real time PCR

6

Description
Aldose Reductase gene expression
Timepoint
Before and three months after intervention
Method of measurement
Real time PCR

Secondary outcomes

1

Description
Vitamin D
Timepoint
Before and three months after intervention
Method of measurement
Electrochemiluminesence

2

Description
calcium
Timepoint
Before and three months after intervention
Method of measurement
Espectrophotometry

3

Description
insulin
Timepoint
Before and three months after intervention
Method of measurement
Electrochemiluminesence

4

Description
A1C
Timepoint
Before and three months after intervention
Method of measurement
Chromatoghraphy

5

Description
TNF
Timepoint
Before and three months after intervention
Method of measurement
Elisa

6

Description
ages
Timepoint
Before and three months after intervention
Method of measurement
Elisa

7

Description
PAI
Timepoint
Before and three months after intervention
Method of measurement
Elisa

8

Description
ykl-40
Timepoint
Before and three months after intervention
Method of measurement
Elisa

9

Description
TG
Timepoint
Before and three months after intervention
Method of measurement
Espectrophotometry

10

Description
cholestrol
Timepoint
Before and three months after intervention
Method of measurement
Espectrophotometry

11

Description
HDL
Timepoint
Before and three months after intervention
Method of measurement
Espectrophotometry

12

Description
LDL
Timepoint
Before and three months after intervention
Method of measurement
Espectrophotometry

13

Description
Diastolic and systolic blood pressure
Timepoint
Before and three months after intervention
Method of measurement
Sphygmomanometer and Stethoscope will be used to measure the blood pressure

14

Description
BMI
Timepoint
Before and three months after intervention
Method of measurement
the formula for BMI is weight in kilograms divided by height in meters squared

15

Description
Insulin resistance
Timepoint
Before and three months after intervention
Method of measurement
HOMA-IR

16

Description
weight
Timepoint
Before and three months after intervention
Method of measurement
seca scale in kilograms

17

Description
Waist
Timepoint
Before and three months after intervention
Method of measurement
Band meters in cm

18

Description
IL6
Timepoint
Before and three months after intervention
Method of measurement
Elisa

Intervention groups

1

Description
Intervention group 1: receive 100 micro gram of vitamin D daily for 3 months
Category
Treatment - Drugs

2

Description
Intervention group 2: receive 100 micro gram of placebo daily for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Research Center, Endocrinology and Metabolism Research Institute
Full name of responsible person
Dr.Rajab
Street address
Clinic of Diabetes, West 17 Shahrivar, North Kargar Ave, Amir Abad City Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.jalali
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Deptartment of Nutrition&dieticsTehran University of Medical Sciences, Poursina avenue
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Email
jalalimahmoud@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Dissatisfaction of participant
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available