

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

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

#### 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/m<sup>2</sup>.  
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

#### 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 Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4293 3057

##### Email address

m-zarei@farabi.tums.ac.ir

##### 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 have 35-65 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/m<sup>2</sup>

**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 completed.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

National ethics committee of biomedical research

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floor 13, Department A ,Ministry of Health and Medical Education, Simaye Iran Ave Qods Town

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Tehran

**Province**

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**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**

Electrochemiluminescence

#### 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**

Electrochemiluminescence

#### 4

**Description**

A1C

**Timepoint**

Before and three months after intervention

**Method of measurement**

Chromatography

#### 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**

cholesterol

**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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##### **Email**

mahnazzareei@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr.jalali

##### **Street address**

Department of Nutrition&dieticsTehran University of Medical Sciences, Poursina avenue

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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

**Full name of responsible person**  
Mahnaz zarei

**Position**  
PhD Student of Biochemistry

**Latest degree**  
Master

**Other areas of specialty/work**  
Biochemistry

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## Person responsible for scientific inquiries

### Contact

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Msc

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Master

**Other areas of specialty/work**

Biochemistry

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## Person responsible for updating data

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**Position**  
student

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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