# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Determining the effect of vitamin D on the expression of inflammatory NLRP3 genes and oxidative stress in Patients with type 2 diabetes

## Protocol summary

**Study aim**

Measurement and comparison of the level of biochemical parameters, the level of vitamin D, the level of oxidative stress indicators, the level of expression of the Nlrp3 gene in the studied groups

**Design**

Clinical trial with control group, double-blind, randomized, phase 3-2 on 68 patients. Block-chain with Excel software was used for randomization.

**Settings and conduct**

First and after 8 weeks of intervention, from each individual, 10 cc of intravenous blood will be taken by a sampler at the hospital (morning blood sample with 12 hours of fasting) and will be divided into CBC vials (containing K2EDTA ) and clots. The samples are immediately transferred to laboratory and serum is separated and stored at freezing (-20. C) and CBC vials are kept at refrigerator (2-6. C).To perform biochemical tests (LDL, HDL, vitamin D and oxides) on the serum sample of the clot tube, and to perform genetic testing and measurement of HbA1C, CBC tube is used (LDL, HDL) tests with kits and The enzymatic method, HbA1C will be measured by Immunoturbidimetry technique and vitamin D will be measured with low luminescence.And for genetic testing, PCR real time technique is used, The status of oxidative stress is assessed with TAC kits by FRAP, Thiol group and MDA by spectrophotometry.

**Participants/Inclusion and exclusion criteria**

Inclusion : The disease (diabetes) has been confirmed by a specialist. At least 5 years have passed since the beginning of their diabetes HbA1C is out of the normal range. Age range 50-65 years The desire to participate in the study Exclusion : Kidney and adrenal gland diseases, thyroid, liver,Systemic Take multivitamins,corticosteroids

**Intervention groups**

Patients were randomly assigned to two groups (n = 34) to receive a dose of 50,000 units of vitamin D or placebo for 8 weeks each week.

**Main outcome variables**

HbA1C؛HDL؛ LDL ؛Nlrp3 ؛Oxidative stress status

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200616047795N1**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**
Update count: **0**

**Registration date**

2020-06-22, 1399/04/02

**Registrant information**

**Name**
Mohammad malekaneh

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-06-22, 1398/04/01

**Expected recruitment end date**

2019-12-21, 1398/09/30

**Actual recruitment start date**

2019-09-23, 1398/07/01

**Actual recruitment end date**

2020-02-13, 1398/11/24

**Trial completion date**

2020-07-20, 1399/04/30

**Scientific title**
Determining the effect of vitamin D on the expression of inflammatory NLRP3 genes and oxidative stress in Patients with type 2 diabetes

**Public title**
Evaluation of the effect of vitamin D on diabetic patients
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The disease (diabetes) has already been confirmed by a specialist. People with diabetes who have had diabetes for at least 5 years The criterion for entering the diabetic group is HbA1C, which is outside the normal range. Age range 50-65 years The desire to participate in the study
**Exclusion criteria:**
Systemic diseases (rheumatoid arthritis ...) that can affect the results. Cancer Taking corticosteroids Thyroid disease Kidney diseases and adrenal glands Liver diseases Multivitamin consumption
**Age**
From **50 years** old to **65 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **68**
Actual sample size reached: **62**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple randomization, block
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Individual participants are more likely to have vitamin D interventions Either Placebo was unaware, but they were well aware of the goals, methods, and beneficial consequences, and the potential dangers of studying, and the problems that could follow. Stop cooperating. And the doctor was aware of the participants' informed and free consent, and patients who were not at risk for drug intervention and people who were deficient in vitamin D were referred by a doctor, but the doctor did not know how the accident happened. Data collection officials and those assessing the outcome were unaware of the type and manner of intervention
**Placebo**
Used
**Assignment**
Other
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Birjand University of Medical Sciences
**Street address**
Ghaffari Street
**City**
Birjand
**Province**
South Khorasan
**Postal code**
۹۷۱۷۸۵۳۵۷۷
**Approval date**
2019-07-23, 1398/05/01
**Ethics committee reference number**
ir,bums.REC1398.140

## Health conditions studied

### 1

**Description of health condition studied**
Type 2 diabetes with vitamin D deficiency
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Vitamin D levels
**Timepoint**
First and after 8 weeks
**Method of measurement**
Vitamin D will be measured with a little luminescence technique

## Secondary outcomes

### 1

**Description**
HDL, LDL, A1C hemoglobin levels, Nlrp3 gene, and oxidative stress status
**Timepoint**
First and after 8 weeks
**Method of measurement**
Tests (LDL, HDL) are performed with kits and enzymatic methods. The A1C Hb will be measured using the immunomturbidometry technique. However, PCR real-time techniques are used for genetic testing, as well as tests for oxidative stress status with TAC antioxidant kits by FRAP, Thiol group, and MDA by spectrophotometry.

## Intervention groups

**1**

**Description**
Intervention group: Vitamin D tablets (1 and 25 hydroxyvitamin D3), every week for 8 weeks at a dose of 50,000 units, a product of Zahravi Pharmaceutical Company (Tabriz)
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Diabetes Clinic
**Full name of responsible person**
Dr. Shayesteh
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## Sponsors / Funding sources

**1**

**Sponsor**
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Birjand University of Medical Sciences
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معاون تحقیقات و فناوری
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Birjand University of Medical Sciences
**Proportion provided by this source**
38
**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**
Persons

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
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Shadi
**Position**
Clinical Biochemistry graduate student
**Latest degree**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Yes - There is 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
**Title and more details about the data/document**
Information about the main consequence or the like can be shared.
**When the data will become available and for how long**
Start the access period from 2021 and after printing the results
**To whom data/document is available**
It will be available for researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
In case of further study in this field and related studies
**From where data/document is obtainable**
Birjand University of Medical Sciences, Central Library
**What processes are involved for a request to access data/document**
It must be pursued through the university
**Comments**