Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1601

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drmalekaneh@bums.ac.ir

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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Sweet Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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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
Full name of responsible person
Shadi
Position
Clinical Biochemistry graduate student
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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