

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Assess the effectiveness of Sodium valproate on level of albuminuria in patient with type 2 diabetes :A double-blind randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of sodium valproate on albuminuria in type 2 diabetic patients through double-blind randomized clinical trial

Design

Clinical trial with control group, double-blind, randomized, phase 1-2 on 60 patients. For randomization, block randomization are used by randomization.com

Settings and conduct

This study is a double-blind randomized clinical trial that will be performed in the clinic of Shahid Motari and the clinic of Shahid Faghihi Hospital affiliated to Shiraz University of Medical Sciences.sodium valproate 200 mg of made by destin company daily in one group and twice a day in another group and also in the control group taking placebo.Valproic acid and placebo have exactly the same packaging and the patient and the prescribing physician will not know the type of prescription drug and only the analyzer is aware of the type of drug used by the patient according to the pre-written codes on the drug.

Participants/Inclusion and exclusion criteria

Entry requirements :Type 2 diabetic patients with microalbuminuria of more than 30 milligram in deciliter with an eGFR of more than 60 milliliter in a minute for 1.73 Square meters. No entry conditions : disturbing factors that affect urinary protein excretion such as hypothyroidism or hyperthyroidism, uncontrolled hypertension or diabetes or history of allergy to sodium valproate

Intervention groups

Patients are divided into three groups to evaluate the effect of sodium valproate on albuminuria: The control group that receives the placebo The group that receives sodium valproate at a dose of 200 milligram per day. The group that receives sodium valproate at a dose of 400 milligram per day.

Main outcome variables

level of microalbuminuria, glomerular filtration rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201023049126N1**

Registration date: **2021-03-30, 1400/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-30, 1400/01/10**

Update count: **0**

Registration date

2021-03-30, 1400/01/10

Registrant information

Name

Seyed Alireza Zomorodian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assess the effectiveness of Sodium valproate on level of albuminuria in patient with type 2 diabetes :A double-blind randomized clinical trial

Public title
Sodium Valproate and Diabetic nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with DMTII albuminuria more than 30mg/dl
Exclusion criteria:
Allergy to valproic acid Significantly abnormal liver function test A history of known mental disorders History of cardiac or liver diseases Females who were lactating, pregnant, or intending to become pregnant during the study. A current history of alcohol addiction or drug abuse including analgesics abnormal blood cells counts eGFR less than 60 ml/min/1.73m2 hemoglobin A1c more than 8 Blood Pressure more than 160/100 mmHg neurologic disease such as seizure use antidepressant or antipsychotic drugs History of GN, renal stone or other renal disease that induced proteinuria active hematologic, rheumatologic or infectious diseases active cancers or tumors uncontrol hypo or hyper thyroidism uncontrol hyper parathyroidism

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The people who enter the study with a block randomization method and using the randomization.com site 60 people are placed in a 20-item block .finally, Sixty people are assigned drugs in three ways.

Blinding (investigator's opinion)
Double blinded

Blinding description
Using a placebo with the same shape, color, smell, taste, and box as sodium valproate, the patient becomes blind to the type of drug (placebo or drug). The researcher who gives the drugs to the patients is not aware of the type of drug prescribed because the shape of the boxes is the same and only the code on the boxes is different. He/She does not aware of What do the codes mean and what kind of medicine does each code indicate.

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Administration Building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran
City
Shiraz
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Fars
Postal code
71348-14336
Approval date
2021-01-02, 1399/10/13
Ethics committee reference number
IR.SUMS.REC.1399.1050

Health conditions studied

1

Description of health condition studied
diabetic nephropathy
ICD-10 code
E11.21
ICD-10 code description
Type 2 diabetes mellitus with diabetic nephropathy

Primary outcomes

1

Description
microalbuminuria
Timepoint
At the beginning of the study, one month, two months and three months after starting the drug
Method of measurement
Measurement of microalbuminuria of urine samples

Secondary outcomes

1

Description
liver function test
Timepoint
At the beginning of the study, one month, two months and three months after starting the drug

Method of measurement

Using the patient's blood sample

2**Description**

complete blood count

Timepoint

At the beginning of the study, one month, two months and three months after starting the drug

Method of measurement

Using the patient's blood sample

Intervention groups**1****Description**

Intervention group1:twenty patients take sodium valproate 200 mg tablet of Destin company daily for 3 months

Category

Treatment - Drugs

2**Description**

Intervention group2: twenty patients take sodium valproate 200 mg of Destin company twice a day for 3 months

Category

Treatment - Drugs

3**Description**

Control group1: Twenty patients take a placebo made by Shiraz School of Pharmacy daily for three months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari clinic

Full name of responsible person

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Web page address**2****Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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

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Person responsible for general inquiries

Contact

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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