Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of loratadine and placebo on urinary albumin excretion in patients with of type 2 diabetes mellitus: a double-blind randomized clinical trial

Protocol summary

Study aim
Determination of the effect of Loratadine on urinary albumin excretion in patients with type 2 diabetes mellitus

Design
Clinical trial with control group, double-blind, randomized, phase 3 on 80 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 Shahid Motari Clinic and Clinic of Shahid Faghihi Hospital affiliated to Shiraz University of Medical Sciences. Loratadine 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
Inclusion criteria: 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. Non-inclusion criteria: disturbing factors that affect urinary protein excretion such as hypothyroidism or hyperthyroidism, uncontrolled hypertension or diabetes.

Intervention groups
Intervention group:Forty patients take Loratadine 10 mg tablet of Daropakhsh company daily for 3 months. Control group: Forty patients take a placebo made by Shiraz School of Pharmacy daily for three months.

Main outcome variables
24- hour urine protein excretion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201014049027N1**
Registration date: **2021-05-14, 1400/02/24**
Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**
Update count: **0**

Registration date
2021-05-14, 1400/02/24

Registrant information

Name
Ali Haghighi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of loratadine and placebo on

urinary albumin excretion in patients with of type 2 diabetes mellitus: a double-blind randomized clinical trial

Public title
Loratadine and Diabetic nephropathy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes mellitus Albuminuria more than 30 mg/dL
Exclusion criteria:
The patients who have increased urinary protein excretion for reasons other than type 2 diabetes eGFR less than 60 ml/min/1.73m2
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The people enter the study with a block randomization method and using the randomization.com site and in this way 80 people are placed in a 40 blocks of size 2 . Finally, eighty people are assigned into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Loratadine and placebo have been packaged in similar forms, then nor patients not physician don't know which one is drug and which one is placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Shiraz University of Medical Science
Street address
Shiraz University of Medical Science; Zand street
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2020-09-21, 1399/06/31
Ethics committee reference number
IR.SUMS.MED.REC.1399.361

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
Urine test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use loratadin 10 mg, dialy for 3 months, manufactured by Daruo-Pakhsh.
Category
Treatment - Drugs

2

Description
Control group: Use one placebo tablet dialy for 3 months manufactured at Shiraz School of Pharmacy
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital

Full name of responsible person
Ali Haghighi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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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
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

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ali Haghighi
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All clinical and para clinical information and analysis of data and study results would be shared with respect to patients' privacy.
When the data will become available and for how long
Unlimited.
To whom data/document is available
All researchers of medical sciences.
Under which criteria data/document could be used
All datas of this research useable for patients managment and later researches.
From where data/document is obtainable
Email to Alihaghighi@sums.ac.ir.
What processes are involved for a request to access data/document
Requested datas sent by email to Alihaghighi@sums.ac.ir.
Comments
No.