

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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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Email address

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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 committee 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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Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

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

Shiraz 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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Shafiee

Position

Associate professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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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.