

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of telmisartan in comparison with valsartan and losartan in the amount of albuminuria in patients with diabetic nephropathy

Protocol summary

Study aim

Determine the effectiveness of telmisartan in reducing albuminuria in patients with type 2 diabetes with recent microalbuminuria compared to valsartan and losartan.

Design

A controlled, parallel-group, randomized, phase 3 clinical trial on 152 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The samples will be selected from patients referred to Valiasr Hospital in Zanjan in 1404. They will be randomly assigned to four treatment groups with one of the drugs losartan 25, valsartan 40, and telmisartan 40 daily for 3 months, while the control group will not receive any medication. At the beginning and at the end of the 3-month treatment period, systolic and diastolic blood pressure, as well as serum Cr, urinary albumin, urinary protein to serum creatinine ratio in the morning, and urinary albumin to serum creatinine ratio in the morning will be measured and calculated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30 to 70 years, history of type 2 diabetes for more than 5 to 10 years, hba1c> 10%, gfr> 60, >30first-morning spot UAC<300 Exclusion criteria: Pregnant women, kidney disease not related to diabetes, history of heart failure, stroke, chronic liver disease, prostate diseases in men, type 1 diabetes,

Intervention groups

Intervention group 1 includes patients with diabetic nephropathy who receive telmisartan intervention. Intervention group 2 includes patients with diabetic nephropathy who receive losartan intervention. Intervention group 3 includes patients with diabetic nephropathy who receive valsartan intervention. Group 4 includes patients with diabetic nephropathy who receive no medication.

Main outcome variables

Albuminuria, blood pressure, serum creatinine levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250711066450N1**

Registration date: **2026-07-09, 1405/04/18**

Registration timing: **retrospective**

Last update: **2026-07-09, 1405/04/18**

Update count: **0**

Registration date

2026-07-09, 1405/04/18

Registrant information

Name

Mohammadali Shahmoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3302 3852

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mohammad68.n121@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-22, 1404/05/31

Expected recruitment end date

2025-09-10, 1404/06/19

Actual recruitment start date

2025-10-01, 1404/07/09

Actual recruitment end date

2025-10-18, 1404/07/26

Trial completion date

2025-12-20, 1404/09/29

Scientific title

Investigating the effect of telmisartan in comparison with valsartan and losartan in the amount of albuminuria in patients with diabetic nephropathy

Public title

Investigating the effect of telmisartan in comparison with valsartan and losartan in patients with diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of type 2 diabetes for more than 5 to 10 years
hemoglobin A1c $\leq 10\%$ GFR > 60 > 30 first-morning spot
UAC < 300

Exclusion criteria:

Pregnant women Presence of kidney disease unrelated to
diabetes CHF CVA chronic liver disease prostatic
diseases diabetes type 1 immunodeficiency diseases

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **152**

Actual sample size reached: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to one of four study groups (telmisartan, losartan, valsartan, or control) using block randomization with a 1:1:1:1 allocation ratio. The random allocation sequence will be generated using Random Allocation Software with a block size of four. The unit of randomization is the individual eligible participant. To ensure allocation concealment, the randomization sequence will be prepared by a person who is not involved in participant recruitment or outcome assessment. The allocation sequence will be kept in sequentially numbered, opaque, sealed envelopes (SNOSE). After confirming eligibility and obtaining written informed consent, the next envelope in sequence will be opened to determine the participant's treatment allocation. The person generating the randomization sequence will have no role in participant enrollment or outcome assessment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medival SciEnces, Jomhuri street, Azadi square, Etemadieh town

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2025-06-30, 1404/04/09

Ethics committee reference number

IR.ZUMS.REC.1404.100

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**

Albuminuria rate in patients with diabetic nephropathy

Timepoint

Before the start of the intervention and at the end of the third month after the intervention

Method of measurement

urine albumin

Secondary outcomes**1****Description**

serume Creatinine

Timepoint

Before the intervention and at the end of the third month of the intervention

Method of measurement

serume Creatinine

Intervention groups

1

Description

Intervention group1: Telmisartan tablets 40 mg(Actoveerco Pharmaceutical Company) daily for 3 months

Category

Treatment - Drugs

2

Description

Intervention group2: Losartan tablets 25 mg(Actoveerco Pharmaceutical Company) daily for 3 months

Category

Treatment - Drugs

3

Description

Intervention group3: Valsartan tablets 40 mg (Actoveerco Pharmaceutical Company)daily for 3 months

Category

Treatment - Drugs

4

Description

Control group: Participants in the control group will not receive any of the study medications (telmisartan, losartan, or valsartan) during the 3-month study period. They will continue their routine standard care, including antidiabetic medications and other usual treatments as prescribed by their treating physician. Blood pressure, serum creatinine, HbA1c, and the urinary albumin-to-creatinine ratio (UACR) will be measured at baseline and at the end of the study and compared with the intervention groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

valiasr hospital

Full name of responsible person

Mohammadali shahmoradi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mehrdad Hamidi

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mohammadali Shamoradi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after the study is completed and individuals are de-identified.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The documents will be usable with reference to the source and the study direction.

From where data/document is obtainable

Email address mohammad68.n121@gmail.com
Mohammadli shahmoradi

What processes are involved for a request to access data/document

After sending the email to the researcher, she will immediately receive the documentation.

Comments