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 ≤10% GFR>60 >30first-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, Jomhouri 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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Shariati blvd,valiasr town
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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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info@zums.ac.ir
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 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
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