Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Empagliflozin on Blood Pressure in Diabetic Patients with Chronic Kidney Disease: A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim

To determine the effect of empagliflozin on blood pressure in diabetic patients with chronic kidney disease and to compare the outcomes with a control group.

Design

A randomized, double-blind, parallel-group, controlled clinical trial (Phase 3) conducted on 40 patients. For randomization, a stratified permuted block design (generated using R software) was employed.

Settings and conduct

Patient recruitment and follow-up will be conducted at the nephrology clinics of Zahedan University of Medical Sciences. Patients will be assigned to treatment groups receiving either empagliflozin (10 mg daily) or placebo (a similar-appearing multivitamin). Patients will be evaluated over three visits (baseline, 6-week, and 12-week visits) according to the protocol by Mayne et al. At each visit, systolic and diastolic blood pressures will be measured. Body weight will be assessed using a standardized and calibrated digital scale. Additionally, to evaluate kidney function, GFR and urinary albumin-to-creatinine ratio will be recorded in the data collection form.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age ≥18 years with T2DM, Diagnosis of CKD (e.g., eGFR 20-60 mL/min/1.73m² or equivalent per study protocol), Hypertension (systolic BP ≥130 mmHg and/or diastolic BP ≥80 mmHg at baseline), Willingness to provide informed consent and comply with follow-up visits. Exclusion Criteria:Type 1 diabetes or secondary hypertension, Acute kidney injury, dialysis dependence, or history of kidney transplantation, Severe comorbidities (heart failure, liver disease, or malignancy), hypersensitivity to SGLT2 inhibitors (e.g., empagliflozin)

Intervention groups

Patients will be divided into two groups: one receiving empagliflozin treatment (10 mg daily) and the other receiving a placebo (a similar-appearing multivitamin).

Main outcome variables

Systolic and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250717066530N1**
Registration date: **2025-07-26, 1404/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-26, 1404/05/04**
Update count: **0**

Registration date

2025-07-26, 1404/05/04

Registrant information

Name

Vida Veysi Bigzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3112 5000

Email address

veisivida0@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Empagliflozin on Blood Pressure in Diabetic Patients with Chronic Kidney Disease: A Double-Blind Randomized Clinical Trial

Public title
Evaluation of the Effect of Empagliflozin on Blood Pressure in Diabetic Patients with Chronic Kidney Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with CKD defined by the standard criterion of eGFR between 20–60 mL/min/1.73 m² at the initial visit Consent to participate in the study

Exclusion criteria:
Patients with polycystic kidney disease and patients undergoing kidney transplantation Use of thiazide diuretics and ARBs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to two groups using permuted block stratified randomization. Initially, eligible patients are categorized based on age and gender in the order of their enrollment.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study employs a double-blind design, where the technician responsible for recording outcomes and the participants are unaware of the intervention being administered.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committees of Zahedan University od Medical Sciences

Street address
Dr. Hesabi Square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2024-10-13, 1403/07/22

Ethics committee reference number
IR.ZAUMS.REC.1403.285

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

2

Description of health condition studied
Diabetic Mellitus Type II

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Systolic blood pressure

Timepoint
At baseline, 6 weeks, and 12 weeks following study initiation

Method of measurement
Systolic blood pressure will be assessed using 24-hour ambulatory blood pressure monitoring (ABPM).

2

Description
Diastolic blood pressure

Timepoint
At baseline, 6 weeks, and 12 weeks following study initiation

Method of measurement
Diastolic blood pressure will be assessed using 24-hour ambulatory blood pressure monitoring (ABPM).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive empagliflozin at a dose of 10 mg daily for a duration of 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients in the placebo group will receive a similar-appearing multivitamin for a duration of 12 weeks.Ask ChatGPT
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology Clinic, Ali Ibn Abi Talib Hospital, Zahedan
Full name of responsible person
Dr. Ali Alidadi
Street address
Persian Gulf Highway
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9816743463
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+98 54 3341 0707
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dralidadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Alireza Ansari Moghadam
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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
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Vida Veisi Bigzadi
Position
Resident of internal medicine
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Associate Professor of Nephrology
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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
Data related to the primary outcome will be shared.

When the data will become available and for how long
From 2025 (1404 in the Iranian calendar) up to one year after publication.

To whom data/document is available
Researchers affiliated with universities

Under which criteria data/document could be used
Under no other circumstances.

From where data/document is obtainable
veisivida0@gmail.com

What processes are involved for a request to access data/document
Upon submission of the request and approval of the applicant’s eligibility, the response will be sent within one week.

Comments