Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effects of empagliflozin and dapagliflozin in patients recently undergone kidney transplantation: A randomized double-blind placebo controlled trial

Protocol summary

Study aim

Investigating the effects of empagliflozin and dapagliflozin in patients with kidney transplantation

Design

150 patients will be randomly assigned to three groups (50 each) using systematic randomization. Their demographic and clinical data will be assessed, and they will receive empagliflozin 10 mg, dapagliflozin 10 mg, or a placebo for six months while continuing standard treatment. Data will be collected via patient records and bedside interviews.

Settings and conduct

After the selection of samples, none of the participants will be informed about the randomization process or group allocation. The empagliflozin, dapagliflozin, and their respective placebos will be identical in shape, color, and size and will be provided to patients in identical packaging. Patients assessments will be conducted at baseline, weekly for the first two months, and biweekly thereafter until the fourth month.

Participants/Inclusion and exclusion criteria

This pilot study will be conducted on 150 participants aged 18 to 80 years who have undergone kidney transplantation and have provided written informed consent. Patients with a history of empagliflozin or dapagliflozin use, renal failure with an eGFR <30 mL/min/1.73 m², hepatic failure with a Child-Pugh score of C, pre-existing type 2 diabetes mellitus, inflammatory or autoimmune diseases, malignancy, pregnancy, lactation, symptomatic hypotension, systolic blood pressure below 100 mmHg or above 180 mmHg, or contraindications to empagliflozin or dapagliflozin will be excluded from the study.

Intervention groups

Patients in groups 1, 2, and 3 will receive empagliflozin 10 mg, dapagliflozin 10 mg, or a placebo daily for 6 months.

Main outcome variables

Investigating and comparing the effectiveness of empagliflozin and dapagliflozin on acute organ rejection and renal and hepatic adverse effects of CNI in patients with kidney transplantation compared to placebo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N13**
Registration date: **2025-06-28, 1404/04/07**
Registration timing: **prospective**

Last update: **2025-06-28, 1404/04/07**
Update count: **0**

Registration date

2025-06-28, 1404/04/07

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-21, 1404/05/30

Expected recruitment end date
2026-02-19, 1404/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effects of empagliflozin and dapagliflozin in patients recently undergone kidney transplantation: A randomized double-blind placebo controlled trial

Public title
Empagliflozin and dapagliflozin in kidney transplantation
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
patients with kidney transplantation aged 18 to 80 consented patients
Exclusion criteria:
Pregnancy Lactation Liver failure Heart failure Contraindications of empagliflozin or dapagliflozin Systolic blood pressure less than 100 Autoinflammatory diseases Malignancy Diabetes mellitus Contraindications of dapagliflozin Systolic blood pressure more than 180 mm Hg
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be carried out using random allocation site (https://www.sealedenvelope.com/simple-randomiser/v1/lists) by blocked randomization method with random block size 6 and 9.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and health care providers are not aware of the type of grouping of patients, and the study drug will be unrecognizable to patients and related treatment staff. A matched placebo is identical to intervention in every aspect, such as appearance, smell, and taste. The only person who will know the type of drug is the coordinator of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2024-09-23, 1403/07/02
Ethics committee reference number
IR.TBZMED.REC.1403.525

Health conditions studied

1

Description of health condition studied
Kidney transplantation
ICD-10 code
Z94.0
ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Acute organ rejection
Timepoint
At the baseline and 2, 4, 8, 12, and 16 weeks after intervention
Method of measurement
biopsy

2

Description
Kidney adverse events of CNI
Timepoint
At the baseline and 2, 4, 8, 12, and 16 weeks after intervention
Method of measurement

Measurement of serum creatinine, GFR, and albumin

3

Description
Liver adverse events of CNI
Timepoint
At the baseline and 2, 4, 8, 12, and 16 weeks after intervention
Method of measurement
Measurement of liver enzyme and albumin levels

Secondary outcomes

1

Description
The incidence of new diabetes mellitus following kidney transplantation
Timepoint
At baseline and 2, 4, 8, 12, and 16 weeks after the intervention
Method of measurement
Measurement of hemoglobin A1C, fasting blood sugar, and two-hour blood sugar

Intervention groups

1

Description
Intervention group: Patients will receive 10mg (Gloripa) of empagliflozin oral once daily for six months with standard treatments
Category
Treatment - Drugs

2

Description
Intervention group: Patients will receive 10mg of dapagliflozin (gloxiga) oral once daily for six months with standard treatments
Category
Treatment - Drugs

3

Description
Control group: Patients will receive placebo daily for six months with standard treatments
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Transplant Center of Tabriz
Full name of responsible person
Dr Afshin Gharekhani
Street address
Imam Reza Transplant Center of Tabriz, Parastar street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Khosro Adibkia
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Golgasht, Daneshghah Street, Tabriz ،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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person

Dr Afshin Gharekhani
Position
Associated professor of Clinical pharmacy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All of the data of an article can be published after making patients unrecognized.
When the data will become available and for how long
After publishing of article until 6 months after publishing of the results
To whom data/document is available
Data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims.
From where data/document is obtainable
Applicants can receive data by sending an E-mail to address of anqarekhani@yahoo.com and get response from Dr. Afshin Gharekhani
What processes are involved for a request to access data/document
After contacting with corresponding author(Dr. Afshin Gharekhani), data will be sent to Tabriz Imam Reza hospital ethics committee and after receiving permission, data will be send to applicants
Comments