Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of evaluation of the safety and effectiveness of SGLT2 inhibitors in new kidney transplant patients

Protocol summary

Study aim

The study will evaluate the effectiveness and safety of SGLT2 inhibitors in managing blood glucose levels, kidney function, graft survival, patient outcomes, and potential side effects in this population.

Design

Controlled clinical trial with parallel groups, open-label, randomized, Phase 1-2 will be conducted on 60 patients. Randomization will be performed using the Rand function in Excel software.

Settings and conduct

In this study, which will be conducted as a randomized clinical trial at Imam Khomeini Hospital in Tehran, kidney transplant recipients will be enrolled based on specific inclusion and exclusion criteria. Each patient will be randomly assigned to designated groups using limited block randomization. The first group will receive treatment with Empagliflozin at a dosage of 10 mg daily following kidney transplantation, while the second group will not receive Empagliflozin. The study will be open-label, and to assess any positive or negative effects of the intervention, patients will be evaluated at the end of the first and third months.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: New Kidney Transplant Age group: 18 to 75 years The individual is capable of adhering to the prescribed medication regimen, with no history of drug sensitivity or previous contraindications. Exclusion Criteria: Allergy to empagliflozin. Type 1 Diabetes Mellitus Urosepsis Lack of Informed Consent GFR less than 20 mL/min

Intervention groups

In the intervention group, patients will be treated with Empagliflozin 10 mg daily after kidney transplantation. The comparison group will not receive Empagliflozin

Main outcome variables

Glomerular Filtration Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101106005113N4**
Registration date: **2025-06-05, 1404/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-05, 1404/03/15**
Update count: **0**

Registration date

2025-06-05, 1404/03/15

Registrant information

Name

Seyyed Mohammad Reza Khatami

Name of organization / entity

Nephrology Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6119 2659

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khatamis@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial of evaluation of the safety and effectiveness of SGLT2 inhibitors in new kidney transplant patients

Public title
Safety and Effectiveness of SGLT2 Inhibitors in Kidney Transplantation Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
New Kidney Transplant Age group 18 to 75 years old Able to adhere to the studied medication regimen (no drug sensitivity or previous contraindications)

Exclusion criteria:
Empagliflozin sensitivity Diabetes Mellitus type 1 Urosepsis Informed Consent Refusal Glomerular filtration rate (GFR) of less than 20 mL/min.

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Approach: Restricted Randomization using Block Randomization. Purpose of Blocking: To balance the number of participants between the intervention group and the control group. Block Configuration: Create 6 blocks, each containing 10 participants (with 5 participants assigned to the intervention group and 5 to the control group within each block). Random Selection of Blocks: Use random number generation tools, like the R programming language, to generate 6 random numbers within the range of 1 to 6. Application of Sealed Envelopes: Record the random sequences on cards and store them in opaque, sealed envelopes, arranged in numerical order.

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
Imam Khomeini Hospital Complex, Tehran University of Medical Sciences (Research Ethics Committee)

Street address
Tehran, at the end of Keshavarz Boulevard, Imam Khomeini Hospital, Kidney Transplant Department.

City
tehran

Province
Tehran

Postal code
1419733141

Approval date
2025-05-20, 1404/02/30

Ethics committee reference number
IR.TUMS.IKHC.REC.1404.102

Health conditions studied

1

Description of health condition studied
Kidney Transplant

ICD-10 code
Z94.0

ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Glomerular filtration rate

Timepoint
Patients will be evaluated at the beginning of the study, as well as one month and three months after initiating treatment with Empagliflozin 10 mg.

Method of measurement
MDRD equation

Secondary outcomes

1

Description
HbA1C

Timepoint
before intervention and 1, 3 , month after intervention

Method of measurement
Laboratory test

2

Description
Urinary tract infections.

Timepoint
before intervention and 1, 3 , month after intervention

Method of measurement
Urine Culture media

3

Description
Microalbuminuria
Timepoint
before intervention and 1, 3 , month after intervention
Method of measurement
Random urine Albumin to Creatinine ratio

4

Description
Acute Transplant Rejection
Timepoint
before intervention and 1, 3 , month after intervention
Method of measurement
Transplanted Kidney Biopsy

Intervention groups

1

Description
Intervention group: Following kidney transplantation and stabilization of kidney function, indicated by a steady serum creatinine level at discharge, the patient will receive a daily dose of 10 mg Empagliflozin from Abidi Pharmaceutical Company for three months, in conjunction with the immunosuppressive regimen.
Category
Treatment - Drugs

2

Description
Control group: Only received an immunosuppressed protocol and did not receive any intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Reza Khatami
Street address
Tehran, at the end of Keshavarz Boulevard, Imam Khomeini Hospital, Kidney Transplant Department.
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Email
khatamis@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dr. Abidi Pharmaceuticals
Full name of responsible person
Dr. Media Shamsaddini
Street address
No. 72, Abidi Blvd. 8th km of Lashgari Exp
City
Tehran
Province
Tehran
Postal code
1389776363
Phone
+98 21 8870 1600
Email
aida.mirkazemii@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dr. Abidi Pharmaceuticals
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Khatami
Position
professor of medicine
Latest degree
Subspecialist
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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from the primary and secondary outcomes of the study will first be provided to the Nephrology Research Center of the university for use by other researchers. Secondly, it will be shared with the funding company to be sent to its central organization (Abidi Pharmaceutical Company) so that international researchers can access this data. Finally, the results of the study will be published as an article.

When the data will become available and for how long

The access period begins 1 months after the results are published.

To whom data/document is available

researchers in the field of medicine and pharmacology

Under which criteria data/document could be used

The use of documents for writing scientific articles or research reports is permitted with proper citation (including the IRCT registration code and the names of the researchers) and contingent upon obtaining written permission from the Nephrology Research Center of Tehran University of Medical Sciences.

From where data/document is obtainable

M R Khatami, Nephrology Research Center, Imam Khomeini hospital khatamis@sina.tums.ac.ir

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

The requests should be sent to Nephrology Research Center, by the name of main researcher and after the evaluation of position of the requester the data will be available for him/her.

Comments