Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Aug 2026

A comparative study of the effect of intravenous mannitol injection during surgery on the rate of delayed transplant performance in kidney transplant recipients in Hashminejad Hospital

Protocol summary

Study aim
Determining the effect of intraoperative intravenous mannitol injection on the rate of delayed graft function in kidney transplant recipients.

Design
This research is a Phase 2-3 randomized controlled clinical trial with a parallel-group, triple-blind design, conducted on 120 kidney transplant recipients. Patients will be randomly allocated to either the intervention or control group using the RAND function in Microsoft Excel.

Settings and conduct
This triple-blind, block-randomized trial at Hasheminejad Hospital will compare intraoperative 20% mannitol versus 0.9% saline in kidney transplant patients. After multidisciplinary approval, patients will be randomized to either group. Identical administration protocols will be used, with patients, anesthesiologists, and outcome assessors blinded to assignment.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: First-time kidney transplant recipient. Age 18–70 years. Surgery performed within the study period. Approval by a multidisciplinary team (Psychiatry, Nephrology, Surgery). Transplant benefits outweigh the risks. Able to tolerate surgery and immunosuppressive drugs. Exclusion Criteria: Undergone renal autotransplantation. Known hypersensitivity to mannitol. Occurrence of any adverse reaction or complication that cannot be controlled during the study.

Intervention groups
The intervention group will receive 20% mannitol solution at a dose of 0.5 mL per kilogram of body weight (concentration: 0.5 mL = 1 gram). The control group will receive 0.9% sodium chloride solution at the same dose of 0.5 mL per kilogram. The maximum total dose of the study solution is limited to 50 mL. A 10 mL bolus of the assigned solution will be administered just before graft reperfusion, and the remaining volume will be infused continuously until the end of the surgery.

Main outcome variables
Delayed Graft Function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251231068512N1**
Registration date: **2026-01-13, 1404/10/23**
Registration timing: **prospective**

Last update: **2026-01-13, 1404/10/23**
Update count: **0**

Registration date
2026-01-13, 1404/10/23

Registrant information

Name
Saber Khoramabadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of intravenous mannitol injection during surgery on the rate of delayed transplant performance in kidney transplant recipients in Hashminejad Hospital

Public title
The effect of intraoperative intravenous mannitol injection on delayed graft function in kidney transplant recipients.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
First-time kidney transplant recipient Age 18–70 years Surgery within the study period Multidisciplinary team approval (Psychiatry, Nephrology, Surgery) Transplant benefits outweigh risks Tolerates surgery and immunosuppression
Exclusion criteria:
Underwent renal autotransplantation Known hypersensitivity to mannitol Any adverse reaction that cannot be controlled during the study
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method: Block randomization will be used. Patients will be allocated to either the intervention (mannitol) or control (placebo) group using the block randomization method. This approach ensures that the number of patients in the two groups remains approximately balanced throughout the study. Unit of Randomization: Individual (patient). Randomization Tool: Microsoft Excel with the RAND function will be used. Random Sequence Generation: To perform block randomization with a block size of 4 in Excel, all possible balanced permutations of two patients allocated to group "A" (e.g., mannitol) and two to group "B" (placebo) are first listed in a column. Next to each permutation, a random number is generated using the RAND function for each row. By sorting the entire list based on the column of random numbers (in ascending or descending order), the final sequence of blocks is determined randomly. This randomized sequence of consecutive 4-patient blocks then forms the master allocation list. Allocation Concealment: To maintain concealment, the allocation list will be stored and implemented using serially numbered, opaque, sealed envelopes or a secure electronic system.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is designed as a triple-blinded trial to prevent any bias in the intervention and outcome assessment. Patients will be unaware of their assignment to the intervention or control group, as the injected solutions (20% mannitol and 0.9% normal saline) will be identical in appearance, volume, and administration method, prepared in identical, unlabeled containers. The anesthesiologist administering the solution will also be blinded to its nature (active drug or placebo), since the preparation and coding of the solutions will be performed by an independent staff member not involved in the trial. Furthermore, the outcome assessor (who records and adjudicates endpoint data such as dialysis requirement, serum creatinine levels, and biopsy results) will remain blinded to the group allocation codes. The allocation sequence will be kept in serially numbered, opaque, sealed envelopes or a secure electronic system and will be disclosed only in the event of a medical emergency.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway, Tehran
City
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Tehran
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1449614535
Approval date
2025-07-22, 1404/04/31
Ethics committee reference number
IR.IUMS.FMD.REC.1404.232

Health conditions studied

1

Description of health condition studied
Kidney transplant
ICD-10 code
T86.12
ICD-10 code description
Kidney transplant failure

Primary outcomes

1

Description
Delayed Graft Function
Timepoint
10 days post-transplant
Method of measurement
Clinical examination

Secondary outcomes

1

Description
Serum creatinine level
Timepoint
Up to 10 days after transplantation
Method of measurement
Test

2

Description
24-hour urine volume
Timepoint
24 hours after receiving the transplant
Method of measurement
Test

3

Description
Deaths
Timepoint
Up to 3 months after transplantation
Method of measurement
Follow-up

4

Description
Cold ischemic time
Timepoint
During the transplant operation
Method of measurement
observation

5

Description
Warm Ischemic Time
Timepoint
During the transplant operation
Method of measurement
observation

Intervention groups

1

Description
Intervention group: the intervention group will receive a 20% Mannitol (D-Mannitol) solution intravenously during surgery. The drug dosage is calculated based on body weight (0.5 mL/kg, equivalent to 0.1 g/kg) and is capped at a maximum of 50 mL. The administration protocol involves the injection of a 10 mL bolus immediately before graft reperfusion, followed by continuous infusion of the remaining volume until the end of the procedure.
Category
Other

2

Description
Control group: The control group will receive 0.9% sodium chloride (normal saline) as an active placebo. The dose, volume (based on 0.5 mL/kg, up to a maximum of 50 mL), and administration protocol (including a 10 mL bolus before graft reperfusion and continued infusion until the end of the procedure) will be exactly the same as for the mannitol group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Hashemi-Nejad Hospital
Full name of responsible person
Saber Khoramabadi
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Vali Asr Street (AJ), above Vanak Square, Shahid Valinejad Alley, Shahid Hashminejad Hospital, tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Saber Khoramabadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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Vali Asr Street (AJ), above Vanak Square, Shahid Valinejad Alley, Shahid Hashminejad Hospital, Tehran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

Not applicable