Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Dapagliflozin in The Prevention of Acute Kidney Injury Caused by Iodinated Contrast Media: A Randomized Placebo-Controlled Clinical Trial

Protocol summary

Study aim
Investigating the effect of Dapagliflozin in preventing nephropathy caused by iodinated contrast media

Design
Phase 3 randomized clinical trial on 100 patients in two control and intervention groups will be 1:1 parallel to the Permuted Block Randomization method and will be double-blind.Random numbers, determination of random blocks and random assignment to groups will be done with Excel software.

Settings and conduct
Imam Reza Hospital A double-blind study of drug prescribers, patients and data collectors

Participants/Inclusion and exclusion criteria
Admission: Patients aged 18 years or older who need CT scan and receive iodinated contras. Exclusion: Pregnant and lactating women, patients with underlying renal failure, heart failure, liver failure , suffering from autoimmune or infectious disease, diabetics with diabetic foot ulcers , with conditions that predispose to ketoacidosis, with pancreatic insufficiency, with osteoporosis, alcoholic patients, patients who take nephrotoxic drugs at the same time, patients with a history of sensitivity to Dapagliflozin or have previously taken Dapagliflozin.

Intervention groups
Administering 10 mg of oral Dapagliflozin once daily in addition to the standard care therapy from 3 days before to 2 days after the receiving iodinated contrast media.

Main outcome variables
KIM 1 (Kidney Injury Molecule1) level in urine BUN (Blood Urea Nitrogen) and creatinine levels in plasma NGAL (Neutrophil Gelatinase Associated Lipocalin) levels in urine and plasma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170609034406N11**
Registration date: **2024-01-25, 1402/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-25, 1402/11/05**
Update count: **0**

Registration date
2024-01-25, 1402/11/05

Registrant information

Name
Afshin Gharekhani

Name of organization / entity
Faculty of Pharmacy/Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 1315

Email address
gharekhania@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-27, 1402/10/06

Expected recruitment end date
2024-12-26, 1403/10/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Dapagliflozin in The Prevention of Acute Kidney Injury Caused by Iodinated Contrast Media: A

Randomized Placebo-Controlled Clinical Trial

Public title
Effect of Dapagliflozin in The Prevention of Iodinated Contrast Media Induced Acute Kidney Injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 18 years or older Patients who are candidates for CT scan and receive Iodized Contrast Agents
Exclusion criteria:
Patients with underlying renal failure with GFR less than 30 Patients with liver failure (Child-Pugh stage B and C) Patients with heart failure Pregnant and lactating women The presence of chronic infection or autoimmune diseases History of taking Dapagliflozin Diabetic patients with Diabetic foot ulcers Patients are susceptible to ketoacidosis Alcoholic patients Patients with pancreatic failure History of allergy to Dapagliflozin Patients with osteoporosis Concomitant use of nephrotoxic drugs such as Calcineurin Inhibitors , Aminoglycosides, Vancomycin, Amphotericin B Participation in other clinical studuies
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **2**
Serum and urine
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted Block Randomization method will be used to assign patients into two treatment and control groups.This study will have 20 blocks equally containing 4 patients allocated to treatment and control group. Random numbers in this study will be generated using Excel software to determine coalitions, and study groups randomly.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted in a double-blind manner, none of the prescribers and patients and investigator and outcome assessor and data collectors will know which of the patients received Dapagliflozin or placebo , and only through the numbers provided by the system was given to patients, it will be diagnosed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Faculty of Pharmacy - Tabriz University of Medical Science
Street address
Research Ethics Committees , 4th floor, Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaburi, Golgasht St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5766414766
Approval date
2023-11-19, 1402/08/28
Ethics committee reference number
IR.TBZMED.PHARMACY.REC.1402.043

Health conditions studied

1

Description of health condition studied
Acute kidney injury caused by iodinated contrast agents
ICD-10 code
N17
ICD-10 code description
Acute kidney failure

Primary outcomes

1

Description
Urine KIM1 (Kidney Injury Molecule-1) level
Timepoint
At the beginning and end of the study
Method of measurement
ELISA Kit

2

Description
Serum BUN (Blood urea nitrogen) and Creatinine level
Timepoint
At the beginning and end of the study
Method of measurement
AutoAnalyzer

3

Description
Urine and Serum NGAL(Neutrophil Gelatinase Associated Lipocalin) level
Timepoint
At the beginning and end of the study
Method of measurement
ELISA Kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Dapagliflozin + standard care): 40 patients will be included in the study according to the inclusion and exclusion criteria, and will recieve 10 mg of Dapagliflozin once daily from 3 days before to 2 days after the receiving iodinated contrast agent along with the standard care recommended by the Iranian Ministry of Health protocol.
Category
Treatment - Drugs

2

Description
Control group (Placebo + standard care): 40 patients will be included in the study according to the inclusion and exclusion criteria, and will recieve the equivalent placebo of 10 mg of Dapagliflozin once daily from 3 days before to 2 days after receiving the iodinated contrast agent along with the standard care recommended by the Iranian Ministry of Health protocol.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Afshin Gharekhani
Street address
Imam Reza General Hospital , Across from Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 7054
Email
gharekhania@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Parviz Shahabi
Street address
No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5147663419
Phone
+98 41 3334 4280
Email
shahabip@tbzmed.ac.ir
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
Afshin Gharekhani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz
City
Tabriz

Province
East Azarbaijan
Postal code
5166614766
Phone
0098413372250
Email
gharekhania@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Afshin Gharekhani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3337 2250
Email
gharekhania@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Sana Norouzi Sari Baghloo
Position
Pharmacy Student
Latest degree
Bachelor
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy , Tabriz University of Medical Science, Daneshgah Street, Tabriz,Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5147663419
Phone
+98 41 3333 7244
Email
sana.nzsb@gamil.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available