

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 contrast. 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)

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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 studies
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

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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 receive 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 receive 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

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No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz

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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

Afshin Gharekhani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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