

# 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 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)

##### 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 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

### 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 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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614756

##### **Phone**

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#### **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

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##### **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

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## Person responsible for scientific inquiries

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Associate professor

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Specialist

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## Person responsible for updating data

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Sana Norouzi Sari Baghloo

**Position**

Pharmacy Student

**Latest degree**

Bachelor

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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