

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the effect of dapagliflozin on preventing contrast-associated acute kidney injury in patients with acute coronary syndrome undergoing angiography (DARIUS); a multicenter, randomized, double-blind, placebo-controlled clinical trial

#### Protocol summary

##### Study aim

Efficacy of dapagliflozin in preventing contrast associated acute kidney injury (CA-AKI) in patients with acute coronary syndrome (ACS) undergoing coronary angiography Effects of dapagliflozin on reducing renal replacement therapy in patients with ACS undergoing coronary angiography

##### Design

This is a Phase III prospective, multicenter, randomized, double-blind, placebo-controlled, clinical trial evaluating the efficacy of dapagliflozin for the prevention of CA-AKI. The study will use parallel assignment intervention model, with randomization in a 1:1 ratio to receive either dapagliflozin or a matched placebo in addition to standard care.

##### Settings and conduct

The study will be conducted at Rajaie hospital and Tehran Heart Center. Both patients and study personnel will be blinded by using matching placebo. Patients will be assigned to one of the intervention groups and will receive it until discharge after the confirmation of diagnosis in the emergency department.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients over 18 years old hospitalized with ACS and candidates for coronary angiography or angioplasty Signed informed consent to participate in the study Exclusion Criteria: Diabetes Type 1 Patients treated with SGLT2 inhibitor Creatinine clearance <25 ml/min Severe liver disease Hypersensitivity to dapagliflozin Patient's non-consent History of recurrent urinary tract infections History of ketoacidosis pregnancy or lactation

##### Intervention groups

Patients in the intervention group will receive 20 mg of dapagliflozin immediately after randomization and before entering the cath lab, followed by 10 mg daily for a

minimum of 48 hours and up to 7 days.

##### Main outcome variables

Primary Outcome The incidence of acute kidney injury according to the KDIGO criteria Secondary Outcomes Need for renal replacement therapy Length of hospital stay

#### General information

##### Reason for update

##### Acronym

DARIUS

##### IRCT registration information

IRCT registration number: **IRCT20181026041471N1**

Registration date: **2024-08-20, 1403/05/30**

Registration timing: **prospective**

Last update: **2024-08-20, 1403/05/30**

Update count: **0**

##### Registration date

2024-08-20, 1403/05/30

##### Registrant information

##### Name

Hessam Kakavand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2260 6951

##### Email address

hessamkakavand@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2024-08-22, 1403/06/01

**Expected recruitment end date**

2026-03-20, 1404/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effect of dapagliflozin on preventing contrast-associated acute kidney injury in patients with acute coronary syndrome undergoing angiography (DARIUS); a multicenter, randomized, double-blind, placebo-controlled clinical trial

**Public title**

The efficacy of dapagliflozin in preventing contrast-associated acute kidney injury

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients over 18 years old hospitalized with acute coronary syndrome (i.e. ST elevation or NST elevation myocardial infarction or unstable angina) diagnosis and candidates for coronary angiography or angioplasty Signed informed consent to participate in the study

**Exclusion criteria:**

Patients previously treated with SGLT2 inhibitor drugs Creatinine clearance less than 25 ml/min Chronic liver disease and cirrhosis (Child-Pugh C) Drug allergy or history of severe hypersensitivity to dapagliflozin or its components Non-consent to participate in the study History of recurrent urinary tract infections History of ketoacidosis Pregnancy or breastfeeding Type 1 diabetes mellitus

**Age**From **18 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**Target sample size: **1500****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomized individually and via an online computer program to one of intervention or control groups after meeting the eligibility criteria. The randomization system will use block randomization

method and the patients will be placed in the intervention or control group in a ratio of 1:1 by the online computer system in blocks of four, and each patient will receive a randomization code and the drug will be provided based on this code. The randomization sheet and the codes assigned to the patients will be designed by a statistician outside the current study, and the researcher will only see the code specified to the patient and will provide the medicine to the ward according to the code. These codes will be broken after the end of the study or based on the data and safety monitoring board (DSMB)'s demand.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

to perform blinding in this study, a matching placebo will be used. The patient's medication will be provided to the department based on the code assigned to the patient in the randomization system and placed in the corresponding patient's medication box, and when the patient is transferred to other departments, his medication will also be delivered to the destination department. None of the researchers, patients and the person who analyzes the final data will know which group the patient is in. The study's DSMB committee will have permission to break the treatment code at any time during the study. Also, during the study, after 25, 50 and 75% of the patients were recruited, the available data were analyzed by the DSMB committee, and this committee can stop the study if there is an increase in complications and harm to the patients.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Qods Ave. and Keshavarz Blvd. junction, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1461884513

**Approval date**

2024-05-21, 1403/03/01

**Ethics committee reference number**

IR.TUMS.THC.REC.1403.018

## Health conditions studied

### 1

#### Description of health condition studied

Acute Coronary Syndrome

#### ICD-10 code

I21

#### ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

## Primary outcomes

### 1

#### Description

The incidence of contrast-associated acute kidney injury defined by KDIGO criteria .

#### Timepoint

7 days after intervention

#### Method of measurement

Lab findings (serum creatinine) and urine output

## Secondary outcomes

### 1

#### Description

Need for renal replacement therapy

#### Timepoint

7 days after intervention

#### Method of measurement

Clinical records

### 2

#### Description

Length of hospitalization

#### Timepoint

Until discharge from hospital

#### Method of measurement

Clinical records

### 3

#### Description

Incidence of adverse drug reactions

#### Timepoint

7 days after randomization

#### Method of measurement

Clinical records

## Intervention groups

### 1

#### Description

Patients in the intervention group will receive 20 mg of dapagliflozin immediately after randomization and before entering the cath lab, followed by 10 mg daily for a minimum of 48 hours and up to 7 days.

## Category

Prevention

### 2

#### Description

Control group: Patients in this group will receive matching placebo (2 tablets before intervention) and then once daily for at least 48 hours and maximum 7 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Rajaei Cardiovascular Medical and Research Institute

##### Full name of responsible person

Hessam Kakavand

##### Street address

Shahid Rajaei Cardiovascular Medical and Research Institute, Vali Asr St. (Aj), next to Mellat Park, Niayesh corner, Tehran.

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Tehran

##### Province

Tehran

##### Postal code

1995614331

##### Phone

+98 912 786 5029

##### Email

hessamkakavand@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Tehran Heart Center

##### Full name of responsible person

Maryam Aghakouchakzadeh

##### Street address

Tehran Heart Center, Jalal junction, North Kargar Ave., Tehran, Iran

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1411713138

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m.aghakouchakzadeh@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Rajaie Cardiovascular Medical and Research Institute

**Full name of responsible person**

Saeideh Mazloomzadeh

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Rajaie Cardiovascular Medical and Research Institute,  
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khalili3806@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rajaie Cardiovascular Medical and Research Institute

**Proportion provided by this source**

50

**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

## 2

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Akbari Sari

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Tehran University of Medical Sciences, Qods Ave.,  
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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**

Tehran University of Medical Sciences

**Proportion provided by this source**

50

**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**

Hessam kakavand

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Hessam kakavand

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Position**  
Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Clinical Pharmacy  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The final results of this study (not individual participant's data) will be published after the end of the study.

### When the data will become available and for how long

After the end of patient recruitment and data analysis

### To whom data/document is available

To principle investigator of other studies

### Under which criteria data/document could be used

The principle investigator of other studies should send their request to the principle investigator of the current study to be evaluated

### From where data/document is obtainable

From the principle investigator  
hessamkakavand@yahoo.com

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

After the requesting a reasonable request to the principle investigator, the data will be sent after one month.

### Comments