Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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1995614331
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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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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, Niayesh Junction, Valiasr Ave., Tehran, Iran
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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
Street address
Tehran University of Medical Sciences, Qods Ave., junction, Keshavarz Blvd, Tehran, Iran
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Postal code
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vcr@sina.tums.ac.ir
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
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Other areas of specialty/work
Others
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Person responsible for updating data

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

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