Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of adding sglt2i in preventing kidney failure in patients receiving contrast in coronary angiography -Interventional - Randomized controlled clinical trial

Protocol summary

Study aim
Investigating the Additive Effect of Sodium-Glucose Cotransporter 2 Inhibitors in Preventing Renal Failure in Patients Receiving Contrast Media During Angiography

Design
A randomized, double-blind, placebo-controlled, parallel-group phase 3 trial. Sample: 150 participants (75 per arm). Intervention: Dapagliflozin 10 mg daily vs. matched placebo, initiated ≥3 days pre-angiography and continued for 72 hours post-procedure.

Settings and conduct
At Shiraz Namazi Hospital, coronary angiography candidates are screened. The intervention group receives dapagliflozin 10 mg/day from 3 days before to 72 hours after angiography. Kidney function is measured at baseline, 24h, 48–72h, and 7 days post-angiography. Primary outcome: contrast-induced acute kidney injury (creatinine increase ≥0.3 mg/dL).

Participants/Inclusion and exclusion criteria
The inclusion criteria are 18 years of age or older, and all patients with normal renal parameters who underwent coronary angiography with contrast agents will be included in the study. In addition, patients with EGFR ≤ 30 mL/min will also be included in this study. Exclusion criteria: Patients with known chronic kidney disease, baseline creatinine greater than 1.5 mg/dL, significant hypotension, anemia, and patients with acute myocardial infarction undergoing emergency PCI

Intervention groups
Six groups based on eGFR strata (>90, 60–90, 30–60 mL/min/1.73m²), each divided into: SGLT2 inhibitor group (dapagliflozin 10 mg daily) Placebo group

Main outcome variables
Change in serum creatinine at 48–72 hours from baseline (pre-contrast) Occurrence of CI-AKI (increase in creatinine ≥0.3 mg/dL or ≥50% within 48–72 hours) Need for renal replacement therapy (dialysis) during follow-up Change in eGFR from baseline Hospital length of stay related to renal complications

General information

Reason for update

Acronym
SPARK

IRCT registration information
IRCT registration number: **IRCT20251230068494N1**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date
2026-05-05, 1405/02/15

Registrant information

Name
hooman hemati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3620 5147

Email address
hmthooman@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-09-20, 1405/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of adding sglt2i in preventing kidney failure in patients receiving contrast in coronary angiography -Interventional - Randomized controlled clinical trial

Public title
Effect of SGLT2 Inhibitors in Preventing Kidney Failure After Angiography
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years or older .Scheduled for coronary angiography (elective or emergency) using iodinated contrast. Have normal renal parameters (eGFR ≥ 60 mL/min/1.73m²) or history of chronic kidney disease with eGFR ≤ 30 mL/min/1.73m².
Exclusion criteria:
Patients with known chronic kidney disease Baseline creatinine greater than 1.5 mg/dL Significant hypotension Anemia Patients with acute myocardial infarction undergoing emergency PCI
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients will be randomly assigned to two intervention groups (SGLT2i recipients) and a control group in a 1:1 ratio. The randomization sequence will be generated using SPSS software. To maintain balance in the number of patients in each group, a block randomization method with variable block sizes will be used. The allocation sequence will be prepared and maintained by an independent person who is not involved in the study implementation process to prevent any bias in allocation.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz, Iran
City
shiraz
Province
Fars
Postal code
7134814336
Approval date
2025-11-29, 1404/09/08
Ethics committee reference number
IR.SUMS.MED.REC.1404.470

Health conditions studied

1

Description of health condition studied
Kidney failure
ICD-10 code
I21.01
ICD-10 code description
ST elevation (STEMI) myocardial infarction involving left main coronary artery

Primary outcomes

1

Description
Incidence of contrast-induced acute kidney injury (CI-AKI), defined as an increase in serum creatinine ≥0.3 mg/dL or ≥50% from baseline within 48–72 hours after angiography.
Timepoint
Patients in both groups will be hospitalized for at least 72 hours after angiography to perform clinical and laboratory assessments (creatinine, eGFR, and metabolic parameters).
Method of measurement
Serum Creatinine: Within the normal range of the reference laboratoryeGFR (Estimated Glomerular Filtration Rate): ≥ 60 mL/min/1.73m²BUN (Blood Urea Nitrogen): Within the normal rangeOther parameters related to kidney function (Na, K, etc.) are also recorded and examined quantitatively.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (SGLT2 inhibitor): In addition to standard care, patients receive empagliflozin 10 mg orally once daily, starting 24 hours before angiography and continuing for 72 hours after angiography.
Category
Treatment - Drugs

2

Description
Control group (Placebo): In addition to standard care, patients receive a matching placebo orally once daily, starting 24 hours before angiography and continuing for 72 hours after angiography.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
namazi hospital
Full name of responsible person
Peyman Izadpanah
Street address
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz, Iran
City
shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3233 5849
Email
Paymanizadpanah@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz, Iran
City
shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3233 5849
Email
mohammadi219@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Peyman Izadpanah
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz, Iran
City
shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3233 5849
Email
Paymanizadpanah@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Peyman Izadpanah

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Cardiology

Street address
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz, Iran

City
shiraz

Province
Fars

Postal code
7134845794

Phone
+98 71 3233 5849

Email
Paymanizadpanah@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Peyman Izadpanah

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Cardiology

Street address
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz, Iran

City
shiraz

Province
Fars

Postal code
7134845794

Phone
+98 71 3233 5849

Email
Paymanizadpanah@gmail.com

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
Yes - There is a plan to make this available

Title and more details about the data/document
Raw study data including demographic characteristics, baseline clinical and laboratory parameters, type and volume of contrast media, SGLT2 inhibitor use, and primary outcome data (serum creatinine changes and incidence of acute kidney injury). All data will be de-identified prior to sharing and will be made available in electronic format solely for research purposes upon reasonable request and approval by the ethics committee.

When the data will become available and for how long
Data will be available starting 6 months after publication of the final study results and will remain accessible for a period of 5 years thereafter.

To whom data/document is available
Researchers affiliated with recognized academic, scientific, or research institutions who submit a formal request with a relevant research proposal and obtain approval from the study ethics committee will be granted access to the data.

Under which criteria data/document could be used
The data may be used solely for research purposes and for conducting secondary scientific analyses related to kidney injury and associated outcomes. Commercial use, re-identification of participants, or use beyond the approved research scope is not permitted. Access is subject to submission of a formal request, a clearly defined research proposal, a written commitment to data confidentiality, and approval by the study ethics committee.

From where data/document is obtainable
Applicants seeking access to study data or documents should contact the Clinical Research Office of Shiraz University of Medical Sciences or the official email of the study data custodian, submitting their request along with a research proposal and a confidentiality agreement.

What processes are involved for a request to access data/document
After submission of a formal request with a research proposal and confidentiality agreement, the request is reviewed by the data custodian. The study ethics committee then evaluates whether the proposed use aligns with research objectives and confidentiality requirements. Upon approval, access to the data or documents is granted in a de-identified format with data protection instructions.

Comments
All provided data and documents will be de-identified, with no personally identifiable information included. Use of the data is restricted to approved research purposes, and any sharing or publication to third parties without ethics committee approval is prohibited.