Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Early Use of Dapagliflozin on the Improvement of Left Atrial Function in Type 2 Diabetic Patients Following Acute Coronary Syndrome

Protocol summary

Study aim

The aim of this study is to evaluate the effect of early administration of dapagliflozin on the improvement of left atrial function in patients with type 2 diabetes following acute coronary syndrome.

Design

This study is a randomized, Double-blind, parallel-group clinical trial with two intervention arms. The sample size for each group was 22, but to increase the power of the study, the research team decided to use 50 samples in each group, which became 55 people after considering a 10% dropout rate.

Settings and conduct

This study will be conducted prospectively and interventional at Imam Khomeini Hospital in Ahvaz. Participants will be enrolled following hospitalization due to acute coronary syndrome and will be followed for six months. All evaluations, including echocardiography and laboratory tests, will be performed at the same center.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes, recent ACS, and LVEF between 30–45% will be eligible if suitable for SGLT2 inhibitor therapy. Exclusion criteria include severe renal (eGFR <20), heart or liver failure, active infections, SGLT2 intolerance, dialysis, valvular disease, diabetic ketoacidosis, or refusal to participate.

Intervention groups

Participants will be divided into two groups: the first group will receive 10 mg of dapagliflozin daily, and the second group will receive standard treatment without the use of SGLT2 inhibitors.

Main outcome variables

The primary outcome variable in this study is the improvement of left atrial function, assessed through echocardiography by measuring parameters such as left atrial volume (LAV) and left atrial emptying fraction (LAEF) before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250302064896N1**
Registration date: **2025-04-17, 1404/01/28**
Registration timing: **prospective**

Last update: **2025-04-17, 1404/01/28**
Update count: **0**

Registration date

2025-04-17, 1404/01/28

Registrant information

Name

Sana Yektania

Name of organization / entity

Ahvaz,jundishapour

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-19, 1404/01/30

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the Early Use of Dapagliflozin on the Improvement of Left Atrial Function in Type 2 Diabetic Patients Following Acute Coronary Syndrome

Public title
Effect of Early Use of Dapagliflozin on Improvement of Left Atrial Function in Patients with Type 2 Diabetes after Acute Coronary Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with type 2 diabetes who have recently experienced an acute coronary syndrome (ACS) and have a left ventricular ejection fraction (LVEF) in the range of 30–45% and are eligible to receive SGLT2 inhibitor therapy will be included. Additionally, these patients must have confirmed left atrial dysfunction based on echocardiographic evaluation, as assessed by specialist physicians during the initial examination. Blood pressure will be monitored before and after treatment due to its potential impact on study outcomes.

Exclusion criteria:
Additionally, all patients in the three groups will receive similar background medical treatments to eliminate the potential confounding effects of these therapies on the studied outcomes.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **55**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process in this study was performed using a specialized randomization website that generates random allocation sequences based on blocks of 4 and 8. Participants were randomly assigned to either the dapagliflozin group or the control group without any investigator involvement in the allocation process. A unique random code was generated for each participant and securely recorded in the system to ensure allocation concealment and prevent selection bias. The allocation codes were placed in sealed envelopes containing the intervention details and opened by an independent individual not involved in the study. This method guarantees proper randomization and complete allocation concealment.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the design of this study, it is anticipated that participants and the treatment team (including physicians and nurses) will be blinded to group allocation. The allocation process is planned to be conducted using confidential random codes by an independent individual. Additionally, the medications will be provided in identical packaging to prevent identification of the groups. Accordingly, the study is expected to be conducted as a double-blind trial to minimize the risk of bias in the results

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS)

Street address
Golestan Highway

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Khouzestan

Postal code
6135715794

Approval date
2025-02-15, 1403/11/27

Ethics committee reference number
IR.AJUMS.REC.1403.612

Health conditions studied

1

Description of health condition studied
Acute ischaemic heart disease, unspecified

ICD-10 code
I24.9

ICD-10 code description
Acute ischemic heart disease, unspecified

Primary outcomes

1

Description
Change in Left Atrial Volume (LAV) is one of the primary outcome variables in this study. It will be measured using

two-dimensional echocardiography based on the area–length method. Left atrial areas from the two- and four-chamber views will be obtained, and LAV will be calculated using the formula: LAV = (0.85 × A1 × A2)/L. This parameter reflects structural changes in the left atrium in response to the intervention (dapagliflozin) and serves as a primary indicator of treatment efficacy.

Timepoint

The primary outcome variable (left atrial volume) will be measured at two time points: 1.At baseline (before the initiation of the intervention) 2. Six months after the start of the intervention Echocardiographic assessment will be performed at both time points.

Method of measurement

The primary outcome variable (left atrial volume) will be measured using a two-dimensional echocardiography device. The volume will be calculated by a cardiologist using the area–length method, based on images obtained from the two-chamber and four-chamber views. The echocardiography machine used will be equipped with advanced capabilities for accurate structural cardiac assessment.

Secondary outcomes

1

Description

Change in estimated glomerular filtration rate (eGFR) is considered one of the secondary outcome variables in this study. This parameter is used to evaluate the effect of dapagliflozin on kidney function in patients with type 2 diabetes following acute coronary syndrome. eGFR will be calculated based on serum creatinine levels using the standard CKD-EPI formula. Measurements will be performed at baseline and again six months after the intervention.

Timepoint

The time points for measuring estimated glomerular filtration rate (eGFR) as a secondary outcome are:1. At baseline (before the start of the intervention) 2. Six months after the initiation of the intervention These time points are selected to assess changes in kidney function in response to dapagliflozin treatment.

Method of measurement

The estimated glomerular filtration rate will be calculated using the standard Chronic Kidney Disease Epidemiology Collaboration formula based on serum creatinine levels. Blood samples will be collected by a laboratory technician, and serum creatinine will be analyzed using an automated laboratory biochemistry analyzer.The eGFR will then be calculated by the physician using the mentioned formula.

Intervention groups

1

Description

Intervention group: In the intervention group, participants will receive 10 milligrams of dapagliflozin once daily, administered orally, starting shortly after the diagnosis of acute coronary syndrome and hospital admission. The treatment will continue for a duration of six months. All other standard treatments for diabetes and cardiovascular disease will be kept consistent between both groups to isolate the effect of dapagliflozin on the study outcomes.

Category

Treatment - Drugs

2

Description

Control group: Control group: Participants in this group will receive standard treatment for type 2 diabetes and cardiovascular disease. This includes the use of medications such as metformin and other approved drugs for blood glucose management, blood pressure control, and lipid regulation. Sodium-glucose co-transporter 2 (SGLT2) inhibitors, including dapagliflozin, will not be included in the treatment regimen of this group. Other concomitant medications will be kept similar to the intervention group to ensure that the isolated effect of dapagliflozin can be accurately assessed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Ahvaz

Full name of responsible person
Mohammad Javad Mohammadtaghizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
This study is funded by the Research and Technology Deputy of Ahvaz Jundishapur University of Medical Sciences. No specific external grant has been allocated.

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Ahvaz Jundishapur University of Medical Sciences (AJUMS)

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

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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
No additional information is available.

Study Protocol
Undecided - It is not yet known if there will be 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