Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of empagliflozin on prevention of atrial fibrillation after coronary artery bypass grafting (CABG) or heart valve replacement: a triple-blind, randomized, placebo-controlled trial

Protocol summary

Study aim
prevention of atrial fibrillation after CABG or valve replacement surgery by adding empagliflozin to drug regimen

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct
80 patients that refer to Imam Reza hospital for heart surgery and complete the inclusion criteria will be included in this triple-blind, randomized, placebo-controlled trial. All of them will be monitored for 72 hrs after surgery and if they show AF rhythm for at least 5 minutes and confirmed by ICU physician, this will be considered as final outcome.

Participants/Inclusion and exclusion criteria
Previous use of empagliflozin or other SGLT2 inhibitor drugs •sever heart failure (Class IV NYHA) • Kidney dysfunction (GFR < 30 ml/min/1.73m2) • Liver dysfunction (LFT > 3ULN) • Very thin people (BMI ≤ 18.5 kg/m2) • Pregnancy • Having a pacemaker • Having AF rhythm at first • History of any heart surgery

Intervention groups
intervention group includes patients taking 10 mg empagliflozin tablets once daily from three days before to three days after surgery. control group includes patients taking placebo tablets two times a day from three days before to three days after surgery.

Main outcome variables
Incidence of AF; hospital stay lenght; High-sensitivity C-reactive protein (hs-CRP) concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120520009801N9**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**
Update count: **0**

Registration date
2022-12-07, 1401/09/16

Registrant information

Name
Amir Hooshang Mohammadpour

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 51 1882 3255

Email address
mohamadpoorah@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of empagliflozin on prevention of atrial fibrillation after coronary artery bypass grafting (CABG) or heart valve replacement: a triple-blind, randomized, placebo-controlled trial

Public title
Evaluation of the effect of empagliflozin on prevention of atrial fibrillation after heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for heart surgery including CABG or valve replacement 70 yr > age > 18 yr Taking ACEIs/ARBs, beta-blockers, statins and aspirin for CABG patients
Exclusion criteria:
History of taking empagliflozin drug before surgery Severe heart failure (NYHA Class IV) Renal failure (30 ≥ GFR) Hepatic failure (hepatic enzymes > 3 times of upper normal limit) pregnancy Have pacemaker Have AF rhythm History of heart surgery Very thin people (BMI ≤ 18.5 kg/m2)
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Alternate block randomization using www.randomization.com. Each block has 4 members and The aforementioned site selects twenty blocks out of quadruple blocks at random so that finally 160patients can be included in the study. The allocation concealment method is also the use of opaque sealed envelopes with random sequences obtained from the random allocation step.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After taking the drug or placebo for three days by the patient who has been kept blind to the use of the drug or placebo, the patient is introduced to a nurse in the hospital and the medication is prescribed by the nurse (therapist). In addition, the evaluator (physician) who is different from the therapist (nurse) and does not know which drug the patient has received and is aware only of the assigned code, performs the relevant evaluations. After registration, the results are given to the person who performs the data analysis in the form of a code, and the data analysis is performed without the knowledge of the data analyzer, and all confidential information is recorded and stored without mentioning the patient's name.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ethic committee of Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
91375-345
Approval date
2022-06-18, 1401/03/28
Ethics committee reference number
IR.MUMS.REC.1401.129

Health conditions studied

1

Description of health condition studied
Atrial fibrillation after heart surgery
ICD-10 code
148
ICD-10 code description
Paroxysmal atrial fibrillation

Primary outcomes

1

Description
The incidence of atrial fibrillation
Timepoint
Through 72 hrs after heart surgery
Method of measurement
Holter monitoring

Secondary outcomes

1

Description
C-Reactive Protein (CRP) blood concentration

Timepoint
Before surgery and 3 days after surgery
Method of measurement
Laboratory

2

Description
The incidence of ventricular and supra-ventricular arrhythmias
Timepoint
Through 72 hrs after heart surgery
Method of measurement
Holter monitoring

3

Description
Lenght of hospital stay
Timepoint
From heart surgery to discharge
Method of measurement
Counting of hospitalizations days

Intervention groups

1

Description
Intervention group: It includes patients who receive 10 mg empagliflozin tablets made by abidi under the brand name Gloripa once daily for three days before to three days after surgery. The drug is taken by the patient himself and at home during the three days before the surgery and during the three days after the surgery by the nurses working in the intensive care unit.
Category
Prevention

2

Description
Control group: It includes patients who receive a placebo once daily three days before to three days after surgery, which has been prepared in the Pharmaceutics Laboratory of Mashhad School of Pharmacy. The drug is taken by the patient himself and at home during the three days before the surgery and during the three days after the surgery by the nurses working in the intensive care unit.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Raza hospital
Full name of responsible person
Amirhooshang Mohamadpoor
Street address
Imam Reza hospital, Imam Reza Square, Ibn-e Sina. Avenue, Mashhad , Iran. City. Mashhad. Province. Razavi Khorasan.
City
Mashhad
Province
Razavi Khorasan
Postal code
91375-345
Phone
+98 51 3854 3031
Email
mohamadpoorah@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
Street address
Vice Chancellor for Research and Technology, third floor of Ghoreshi building, next to Hoveyzeh Cinema, University Street, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
GhayourM@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/moavenat/2021-04-06-05-57-55
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Batool Zarei

Position
Clinical Pharmacy Assistant

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

Street address
Fcaulty of Pharmacy, Azadi Sq, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948954

Phone
+98 51 3180 1100

Email
zareb982@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Amir Hooshang Mohammadpour

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Mashhad University of Medical Sciences

City
Mashhad

Province
Razavi Khorasan

Postal code
6519472972

Phone
+98 51 1882 3255

Fax
+98 51 1882 3251

Email
mohamadpoorah@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Amir Hooshang Mohammadpour

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Mashhad University of Medical Sciences

City
Mashhad

Province
Razavi Khorasan

Postal code
6519472972

Phone
+98 51 1882 3255

Fax
+98 51 1882 3251

Email
mohamadpoorah@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this 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
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
all collected deidentified IPD

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
only available for people working in academic institutions

Under which criteria data/document could be used
only available for people working in academic institutions and there is not another condition

From where data/document is obtainable
Amirhushang mohamadpoor
mohamadpoorah@mums.ac.ir

What processes are involved for a request to access data/document
Reply to email within a maximum of one week

Comments