

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		the patient's name.	
Public title	Evaluation of the effect of empagliflozin on prevention of atrial fibrillation after heart surgery	Placebo	Used
Purpose	Prevention	Assignment	Parallel
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)	Other design features	
Age	From 18 years old to 70 years old	Secondary Ids	
Gender	Both	empty	
Phase	2	Ethics committees	
Groups that have been masked	- Participant - Care provider - Outcome assessor	1	
Sample size	Target sample size: 160	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	
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.	Ethics committee of Mashhad University of Medical Sciences	
Blinding (investigator's opinion)	Triple blinded	Street address	
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	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**

Length 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.

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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 Ghoreishi building, next to Hoveyze Cinema, University Street, Mashhad

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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

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Mashhad University of Medical Sciences

Full name of responsible person

Amir Hooshang Mohammadpour

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

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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

Person responsible for updating data

Contact

Name of organization / entity