Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluating the effect of empagliflozin on blood pressure, cardiovascular events, mortality and renal parameters in patients undergoing coronary artery bypass surgery admitted to the A coronary care unit

Protocol summary

Study aim
Evaluating the effect of empagliflozin on blood pressure, cardiovascular events, mortality and renal parameters in patients undergoing coronary artery bypass surgery

Design
Double-blind, randomized, placebo-controlled clinical

Settings and conduct
This study will be conducted in the intensive care unit of Afshar Hospital in Yazd. The patients will be divided into two groups receiving Empagliflozin tablet and placebo by random permutation block method. Each patient will be identified with a number and the list of numbers of people who should be placed in each group will be given to the nurses and the participants, researchers, doctors And the data collectors will be unaware of this list.

Participants/Inclusion and exclusion criteria
Input criteria include:Patients undergoing coronary artery bypass surgery Not being allergic to empagliflozin Exclusion criteria include:Patients who cannot get enough information with echocardiography History of taking pioglitazone at least 8 weeks before entering the study Glomerular filtration rate less than 30 mg per minute per 1.73 square meters of body surface based on the CKD-EPI formula Pregnant or lactating women

Intervention groups
intervention group: Recipients of empagliflozin 10 mg tablets from Abidi Pharmaceutical Company receive one empagliflozin tablet orally a few hours after coronary artery bypass surgery to reduce blood pressure, cardiovascular events, mortality, and control kidney parameters control group: The recipients of a placebo prepared in the pharmaceutical laboratory of the Yazd Faculty of Pharmacy in the same size and color as the empagliflozin tablet, a few hours after coronary bypass surgery, take a 10 mg tablet orally to reduce blood pressure, cardiovascular events, mortality and Renal controls

Main outcome variables
The rate of reduction of blood pressure, cardiovascular events, mortality and control of renal parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190911044744N3**
Registration date: **2023-12-03, 1402/09/12**
Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**
Update count: **0**

Registration date
2023-12-03, 1402/09/12

Registrant information

Name
Ehsan Mirzaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 1820 5885

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ehsan.mirzaei.1369@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-01, 1402/10/11

Expected recruitment end date
2024-06-30, 1403/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of empagliflozin on blood pressure, cardiovascular events, mortality and renal parameters in patients undergoing coronary artery bypass surgery admitted to the A coronary care unit

Public title
Effect of empagliflozin on blood pressure, cardiovascular events, mortality and renal parameters
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing coronary artery bypass surgery Not being allergic to empagliflozin
Exclusion criteria:
Patients who cannot get enough information with echocardiography History of taking pioglitazone at least 8 weeks before entering the study Glomerular filtration rate less than 30 mg per minute per 1.73 square meters of body surface based on the CKD-EPI formula Pregnant or lactating women
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are divided into 25-person groups.using the statistical software,25 out of 50 patients are randomly assigned to treatment group and 25 to placebo group. Unit of randomization: Individual. Tools used in randomization:computer software
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants, the principle investigator, the physicians and the data collectors are blinded. The patients who are going to receive the drug or placebo , are determined by numbers and these numbers are given to the head nurse and nurses of surgery department.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yazd University of Medical Sciences
Street address
Faculty of Pharmacy,Yazd, Shohada gomnam St., Alam Square
City
Yazd
Province
Yazd
Postal code
8915173149
Approval date
2023-06-26, 1402/04/05
Ethics committee reference number
IR.SSU.MEDICINE.REC.1402.139

Health conditions studied

1

Description of health condition studied
Patients undergoing coronary artery bypass surgery
ICD-10 code
T82.9
ICD-10 code description
Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description
Reduction of blood pressure
Timepoint
Daily
Method of measurement
Mercury pressure gauge

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Recipients of empagliflozin 10 mg

tablets from Abidi Pharmaceutical Company receive one empagliflozin tablet orally a few hours after coronary artery bypass surgery to reduce blood pressure, cardiovascular events, mortality, and control kidney parameters

Category

Treatment - Drugs

2

Description

Control group: The recipients of a placebo prepared in the pharmaceutical laboratory of the Yazd Faculty of Pharmacy in the same size and color as the empagliflozin tablet, a few hours after coronary bypass surgery, take a 10 mg tablet orally to reduce blood pressure, cardiovascular events, mortality and Renal controls

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Ehsan Mirzaei

Street address

Yazd-Jomhouri Blvd

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Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Parisa Naseri

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

1

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

Yazd University of Medical Sciences

Full name of responsible person

Ehsan Mirzaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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