

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of empagliflozin in preventing myocardial damage in patients undergoing percutaneous coronary intervention: a double-blind randomized clinical trial

Protocol summary

Study aim

Evaluating the effects of empagliflozin in preventing myocardial damage in patients undergoing percutaneous coronary intervention

Design

This study is a clinical trial with a control group with parallel and double-blind groups. Phase 3 of the study will be conducted on 90 patients with ischemic heart diseases who undergo angioplasty. Patients are divided randomly, using table of random numbers into two intervention groups with empagliflozin (45 people) and the control group, placebo (45 people)

Settings and conduct

Patients with acute myocardial infarction at the Department of Cardiology, Madani Hospital, Tabriz, Iran, were chosen. In this double-blind study, the clinical care and patient were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

All consented patients with ischemic heart diseases aged 18-80 and undergoing of angioplasty and stent insertion will be entered and if history of open heart surgery in the last 3 months and inability in filling and understanding of the consent form in filling and understanding of the consent form will be prohibited from entering the study.

Intervention groups

Intervention group: The recipient of empagliflozin 25 mg tablets manufactured by Farmashi Pharmaceutical Company, Iran, one day and one to two hours before coronary intervention. The placebo are prescribed the day before and 1-2 hours before the intervention

Main outcome variables

The level of cTnI and hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221102056378N1**

Registration date: **2022-11-07, 1401/08/16**

Registration timing: **prospective**

Last update: **2022-11-07, 1401/08/16**

Update count: **0**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Hosein Behzad Vakilabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3554 1221

Email address

hbehzad.pharma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-11, 1401/08/20

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of empagliflozin in preventing myocardial damage in patients undergoing percutaneous coronary intervention: a double-blind randomized clinical trial

Public title

Evaluating the effects of empagliflozin in preventing myocardial damage in patients undergoing percutaneous coronary intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-80 years Ischemic heart diseases patients candidate for angioplasty and stentstent insertion Filling of consent form

Exclusion criteria:

History of infarction History of open heart surgery in the last 3 months Renal dysfunction Dialysis Failed History of Coronary Angioplasty cardiogenic shock cancer Liver failure Autoimmune disease Pregnancy History of serious allergy to empagliflozin Inability in filling and understanding of the consent form

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are divided into two groups of 45 people using the Graphpad prism software and 1:1 randomization, group A as the intervention group and group B as the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study was double-blind and coded A and B, and the participants and the percutaneous coronary surgeon will not know the type of grouping. The intervention group will receive empagliflozin 25 mg and the control group will receive placebo, but they will receive drugs with code A and B. All participants will undergo percutaneous coronary surgery by the same team and the same method.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor; Central Building of Number2; Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2022-10-29, 1401/08/07

Ethics committee reference number

IR.TBZMED.REC.1401.673

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

429.2

ICD-10 code description

Cardiovascular disease, unspecified

Primary outcomes

1

Description

cTnl level

Timepoint

8 hours and 24 hours after the intervention

Method of measurement

ELISA kits

2

Description

hs-CRP level

Timepoint

24 hours after the intervention

Method of measurement

ELISA kits

Secondary outcomes

1

Description

Major Adverse Cardiac Effects
Timepoint
1 month after hospital discharge
Method of measurement
Follow up by phone

Intervention groups

1

Description

Intervention group: The recipient of empagliflozin 25 mg tablets manufactured by Farmashi Pharmaceutical Company, Iran, one day and one to two hours before coronary intervention.

Category

Prevention

2

Description

Control group: The placebo are prescribed the day before and 1-2 hours before the intervention

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Hossein Behzad Vakilabad

Street address

Shahid Madani Hospital, Daneshgah st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hossein Behzad Vakilabad

Position

Clinical Specialist Assistant

Latest degree

Specialist

Other areas of specialty/work

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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