Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Investigating the effect of Empagliflozin on outcomes of patients with myocardial infarction undergoing primary Percutaneous coronary intervention (PCI):a randomized double-blind clinical trial with placebo

Protocol summary

Study aim

Investigating the effect of Empagliflozin on outcomes of patients with myocardial infarction undergoing primary PCI-a randomized double-blind clinical trial with placebo

Design

Double blind, randomized Clinical trial (phase 3) with control and parallel groups on 54 patients. https://www.sealedenvelope.com is used for randomization

Settings and conduct

Double-blind clinical trial including patients with ST-elevation myocardial infarction (STEMI) undergoing successful Primary Percutaneous Coronary Intervention (PCI) in rasht Heshmat hospital.

Participants/Inclusion and exclusion criteria

This is a clinical trial including patients with STEMI undergoing successful Primary PCI in Rasht Heshmat hospital. In all control ad intervention groups, MACE, LVEF at first admission day and after 40-day follow up, recurrent angina and rehospitalization will be checked. Inclusion criteria: 1. patients with STEMI undergoing successful Primary PCI 2. .Based on NYHA functional class I,II,III 3. Consciously satisfaction Exclusion criteria: 1. Failure of primary PCI 2. Empagliflozin contraindications 3. Valvular heart disease with moderate and higher severity 4. Patients who need hemodynamic support during hospitalization 5. Not willing to continue participation in study 6. Receiving drugs ,eg NSAIDs which can not be denied

Intervention groups

Intervention group: Receiving Empagliflozin 10 mg 1 tablet daily. Made by ACTOVER co. Control group: Receiving Placebo (cellulose micro crystal tablet). 1 tablet daily.

Main outcome variables

Major adverse cardiac events (MACE) including stroke, cardiac mortality, reinfarction during 40-day follow up

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055645N7**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **prospective**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name

Fatemeh Baharvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 13 3361 8177

Email address

dr.baharcardio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-09-06, 1403/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of Empagliflozin on outcomes of patients with myocardial infarction undergoing primary Percutaneous coronary intervention (PCI):a randomized double-blind clinical trial with placebo

Public title
The effect of Empagliflozin on outcomes of patients with myocardial infarction undergoing primary PCI

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ST segment elevation myocardial infarction (STEMI) undergoing successful Primary PCI without complications Based on New York Heart Association (NYHA) functional class I,II,III Informed consent for participation in study

Exclusion criteria:
Failure of primary PCI Empagliflozin contraindications Valvular heart disease with moderate and higher severity Patients who need hemodynamic support during hospitalization Not willing to continue participation in study Receiving drugs ,eg Non-steroidal anti-inflammatory drugs (NSAIDs) which can not be denied

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 54 patients according to inclusion criteria, with block randomization group with 1:1 ratio as 2 groups(A: intervention and B: placebo) will enter this study. with Blocking randomization we give each patient a number from 1 to 54. Then a table with 9 rows named block that each block has 6 segments, will be considered and then the numbers will be placed respectively in the rows. After all numbers placed in blocks, all patients with code A, receive drug andpatients with code B receive placebo. https://www.sealedenvelope.com is used for randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and researchers are blind. A third person out of the study, based on randomization allocates the placebo and drug to researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Guilan University of Medical Sciences

Street address
Namjoo

City
Rasht

Province
Guilan

Postal code
41446-66949

Approval date
2024-01-17, 1402/10/27

Ethics committee reference number
IR.GUMS.REC.1402.530

Health conditions studied

1

Description of health condition studied
ST Elevation myocardial infarction

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Myocardial reinfarction

Timepoint
During 40-day follow up

Method of measurement
According to symptoms and ECG findings

2

Description
Stroke

Timepoint
During 40-day follow up

Method of measurement
According to symptoms and physical examinations

3

Description
Cardiac mortality

Timepoint

During 40-day follow up

Method of measurement

Cardiac death according to AHA guideline determined as paroxysmal cardiac arrest with no respiratory and circulatory response

Secondary outcomes

1

Description

Ejection fraction

Timepoint

During 40-day follow up

Method of measurement

By echocardiography

2

Description

Systolic heart failure

Timepoint

During 40-day follow up

Method of measurement

By echocardiography

3

Description

Re admission

Timepoint

During 40-day follow up

Method of measurement

Documented records

4

Description

Angina

Timepoint

During 40-day follow up

Method of measurement

History

5

Description

Second revascularization

Timepoint

During 40-day follow up

Method of measurement

Based on symptoms ECG and echocardiographic findings

6

Description

Empagliflozin complications

Timepoint

During 40-day follow up

Method of measurement

Based on history, symptoms and echocardiography findings.

Intervention groups

1

Description

Intervention group: Receiving Empagliflozin 10 mg 1 tablet daily. Made by Actover co.

Category

Treatment - Drugs

2

Description

Control group: Receiving Placebo (cellulose micro crystal tablet). 1 tablet daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Heart Hospital

Full name of responsible person

Fatemeh Baharvand

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Kooye Bayani

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41939-55588

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Ramyar Farzan

Street address

Parastar

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Rasht

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Guilan

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41937-13111

Phone

+98 13 3334 6489

Email

riasat@gums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Fatemeh Baharvand

Position
Assistant Professor of Interventional Cardiology

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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Person responsible for updating data

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Sharing plan

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

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be 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 data except personal information (name, contact number, file number) can be published.

When the data will become available and for how long
After publishing the results

To whom data/document is available
Available to service providers such as doctors and nurses.

Under which criteria data/document could be used

After obtaining permission from the project manager, the information will be usable.

From where data/document is obtainable

Project manager

What processes are involved for a request to access data/document

By email to the project manager

Comments

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