

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of Empagliflozin on left ventricular ejection fraction in non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary PCI

Protocol summary

Study aim

Evaluation of the effect of empagliflozin on left ventricular ejection fraction in non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary percutaneous coronary intervention(PCI)

Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 64 patients Randomization using Randomization.com

Settings and conduct

This study will perform in the heart ward of Ghaem Hospital in Mashhad. Patients are randomly assigned to Empagliflozin and placebo groups. Patients and the main researcher are unaware of groups assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-diabetic patients, Patients with ejection fraction ≤ 40 , Patients with Anterior ST elevation Myocardial infarction, Patients undergoing primary Percutaneous coronary intervention(PCI), The possibility of follow up patients for echocardiography, Consent to admission to the study Exclusion criteria: Patients who are candidates for medical therapy after angiography, Patients who are candidates for CABG after angiography, Patients with a history of clinical heart failure, patients with a history of anterior STEMI, Patients with a history of PCI on LAD

Intervention groups

Intervention group: Non-diabetic Patients with acute anterior ST-elevation myocardial infarction treated with primary Percutaneous coronary intervention(PCI) receiving Empagliflozin 10 mg once daily for 40 days along with common treatments. Placebo group: Non-diabetic patients with acute anterior ST-elevation MI treated with primary PCI receiving a placebo tablets once daily for 40 days along with common treatments

Main outcome variables

Ejection fraction of left ventricle at the beginning of the

study and after 40 days of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056950N1**

Registration date: **2023-01-14, 1401/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-14, 1401/10/24**

Update count: **0**

Registration date

2023-01-14, 1401/10/24

Registrant information

Name

Bahar Moshfegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3844 4519

Email address

moshfeghb70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-12, 1401/10/22

Expected recruitment end date

2025-01-11, 1403/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Empagliflozin on left ventricular ejection fraction in non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary PCI

Public title

The effect of Empagliflozin on left ventricular ejection fraction in non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary PCI

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-Diabetic patients Patients with ejection fraction \leq 40 Patients with anterior ST elevation myocardial infarction Patients undergoing primary percutaneous coronary intervention(PCI) The possibility of patient follow up for electrocardiography Consent to admission to the study

Exclusion criteria:

Patients who are candidates for medical therapy after angiography Patients who are candidates for CABG after angiography patients with a history of clinical heart failure patients with a history of Anterior STEMI Patients with a history of PCI on LAD

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 16 blocks according to the sample size of 64. Then random numbers between 1 and 16 are selected according to the randomization site Randomization.com and finally, the treatment allocation list is determined based on the random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.

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

Qurashi Building, Next to Hoveyze Cinema, University Street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.522

Health conditions studied**1****Description of health condition studied**

Acute anterior ST elevation Myocardial infarction treated with primary PCI

ICD-10 code

I21.0

ICD-10 code description

ST elevation (STEMI) myocardial infarction of anterior wall

Primary outcomes**1****Description**

Ejection fraction of left ventricle

Timepoint

Ejection fraction of left ventricle at the beginning of the study and after 40 days of treatment.

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary PCI receiving Empagliflozin 10 mg once daily for 40 days

Category

Treatment - Drugs

2

Description

Control group: Non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary PCI receiving a placebo tablets once daily for 40 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital in Mashhad

Full name of responsible person

leila bigdelu

Street address

Ghaem hospital, Ahmadabad Blvd, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour-Mobarhan

Street address

Qurashi Building, Next to Hoveyze Cinema,
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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

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

Bahar moshfegh

Position

Residency

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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