# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 Randomaization.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 assignation.

**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≤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 Randomaization.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**
Ethic's committee of Mashhad University of Medical Sciences

**Street address**
Qurashi Building, Next to Hoveyzeh 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**
Echocardioghraphy

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group:Non-diabetic patients with acute anterior ST elevation Myocardial infarction treated with primary PCI receiving Empagliflozin10 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**
Ghaeem hospital, Ahmadabad Blvd, Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9138813944
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+98 51 3801 2739
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www.moshfeghb70@gmail.com

## 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 Hoveyzeh Cinema, University Street, Mashhad
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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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No. 1.54, Mohtashami 18
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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