Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of oral empagliflozin and placebo on cardiovascular function and quality of life in patients with acute myocardial infarction: a randomized, double-blind clinical trial.

Protocol summary

Study aim

This research aims to determine the effect of empagliflozin on clinical, echocardiographic, and laboratory findings in patients with acute myocardial infarction.

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized by random numbers table, phase 2 on 354 patients.

Settings and conduct

This research is a double-blind clinical trial study, which will be conducted in Hamedan Farshchian Heart and Vascular Hospital. In order to make the study blind (double-blind), the medicine of the patients in the two intervention and control groups, with the coordination of the pharmacy, is poured into capsules of the same color and size and delivered to the researcher with a numerical code (1 and 2). This numerical code is hidden from the researcher and patient and will be revealed only after research and data analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of ST elevation MI; Glomerular filtration rate (rGFR) more than 30; Systolic blood pressure before the first dose of the drug more than 110; Diastolic blood pressure before the first dose of medicine more than 70; The first dose of drug administration is less than 72 hours after the occurrence of an acute stroke. Exclusion criteria: DM other than type2; History of diabetic ketoacidosis; Hemodynamic instability; urinary tract infection; treatment with SGLT2 inhibitors.

Intervention groups

Intervention group: With the coordination of an internist, patients receive empagliflozin at a dose of 10 mg per day (single dose) for 3-5 days. Control group: During this period, the patients in the placebo group will receive a placebo, which is composed of starch compounds and without side effects, and it will be the same amount of 10 mg once a day.

Main outcome variables

Quality of life, cardiovascular function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230501058035N2**
Registration date: **2023-09-23, 1402/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-23, 1402/07/01**
Update count: **0**

Registration date

2023-09-23, 1402/07/01

Registrant information

Name

Ramin Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

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raminmn4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-08-31, 1403/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral empagliflozin and placebo on cardiovascular function and quality of life in patients with acute myocardial infarction: a randomized, double-blind clinical trial.

Public title

The effectiveness of empagliflozin in patients with acute myocardial infarction

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of ST elevation MI acute myocardial infarction by a cardiologist based on clinical variables and ECG Glomerular filtration rate (rGFR) more than 30 Systolic blood pressure before the first dose of the drug more than 110 Diastolic blood pressure before the first dose of medicine more than 70 The first dose of drug administration less than 72 hours after the occurrence of an acute stroke

Exclusion criteria:

People with diabetes other than type 2 History of diabetic ketoacidosis Hemodynamic instability caused by intravenous administration of catecholamine, calcium sensitizers, or phosphodiesterase inhibitors Acute symptomatic urinary tract infection Genital infection Continuous treatment with SGLT2 inhibitors Being treated with any SGLT-2 inhibitor (dapagliflozin, canagliflozin, empagliflozin) four weeks before the screening visit. Known allergy to SGLT-2 inhibitors Severe hypoglycemia in the last six months treated with insulin or sulfonylurea Symptomatic acute urinary tract infection (UTI) or genital infection Patients currently receiving treatment with any SGLT-2 inhibitor (dapagliflozin, canagliflozin, empagliflozin).

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **354**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be done as a simple randomization, using a table of random numbers. In this method, the study members are numbered from 001 to N, then a row and a column of the table are randomly selected. The intersection point of the selected row and column is the starting point of sampling. From this point, a plus or a cross is drawn. All the numbers on the plus or cross are selected as members of the sample.

Blinding (investigator's opinion)

Double blinded

Blinding description

To make the study blind (double-blind), the medicine of the patients in the two intervention and control groups, with the coordination of the pharmacy, is poured into similar capsules in terms of color and size and delivered to the researcher with a numerical code (1 and 2). This numerical code is hidden from the researcher and patient and will be revealed only after research and data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

No 5, Hamadan University of Medical Sciences, Shahid Fahmideh street

City

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Province

Hamadan

Postal code

6517838736

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.UMSHA.REC.1402.276

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I22.9

ICD-10 code description

Subsequent ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description
Cardiovascular function in echocardiography
Timepoint
The systolic and diastolic function of the left ventricle of the heart is measured in two stages (before the intervention and then 4 to 6 weeks after discharge from the hospital).
Method of measurement
Using an echocardiography device using the Simpson method

2

Description
Quality of life with SF36 questioner
Timepoint
Before and after interventions
Method of measurement
SF36 questioner

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Medical intervention with EMPAGLIFLOZIN KHARAZMI 10 MG Tablet per day (single dose) for 3-5 days.
Category
Treatment - Drugs

2

Description
Control group: The patients in the placebo group will receive that the composition is starch compounds without side effects and it will be the same amount of 10 mg once a day for 3-5 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Cardiology subspecialty medical center
Full name of responsible person
Amirhossein Yazdi
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Shahid Fahmideh Ave., Pazhouhesh square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Shaghaghi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Nuclear Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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

Title and more details about the data/document
Only a part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long
The access period starts six months after the results are published

To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Our data will be available to all scientific researchers who request via official email.

From where data/document is obtainable
z.shaghaghi@umsha.ac.ur via email

What processes are involved for a request to access data/document
Researchers will receive the data by sending a data access request six months after the article's publication by sending an email to z.shaghaghi@umsha.ac.ur.

Comments