

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation Effects of Dapagliflozin and Empagliflozin in Nondiabetic Patients with Left Ventricular Systolic Dysfunction following ST Elevation Myocardial Infarction : A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation Effects of Dapagliflozin and Empagliflozin in Nondiabetic Patients with Left Ventricular Systolic Dysfunction following ST Elevation Myocardial Infarction : A Randomized Clinical Trial

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 75 patients. Randomization was performed using block randomization method by an independent person.

Settings and conduct

This study is a randomized clinical trial on a total of 75 non-diabetic patients with left ventricular systolic dysfunction following ST-elevated myocardial infarction who have attended the Shahid Madani clinic of Tabriz University of Medical Science. Patients in the first and second intervention groups received empagliflozin 10 mg, dapagliflozin 10 mg respectively, and in the control group, placebo for 40 days. Patients will then be compared regarding serum levels of hs-CRP and NT-proBNP, NYHA Functional Classification, and cardiac ejection fraction.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Heart Failure with Reduced Ejection Fraction 2. Aged 18 to 80 years 3. Consented patients. Exclusion criteria: 1. Pregnancy 2. Lactation 3. Liver failure 4. Renal failure (estimated glomerular filtration rate less than 30 ml/min) 5. Patients with a history of taking dapagliflozin or empagliflozin 6. Diabetes mellitus 7. Contraindications of dapagliflozin or empagliflozin 8. Inflammatory and autoimmune diseases 9. Systolic blood pressure less than 100 or more than 180 mm Hg 10. Symptomatic hypotension 11. Malignancy

Intervention groups

In the intervention group 1 patients will receive oral dapagliflozin 10 mg/day and in the intervention group 2 patients will receive oral empagliflozin 10 mg/day for 40

days along with standard treatments.

Main outcome variables

1. NYHA Functional Classification
2. NT-proBNP
3. hs-CRP
4. Ejection fraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N45**

Registration date: **2024-02-27, 1402/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-27, 1402/12/08**

Update count: **0**

Registration date

2024-02-27, 1402/12/08

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

tentezarimaleki@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Effects of Dapagliflozin and Empagliflozin in Nondiabetic Patients with Left Ventricular Systolic Dysfunction following ST Elevation Myocardial Infarction : A Randomized Clinical Trial

Public title

Effects of Dapagliflozin and Empagliflozin in Myocardial Dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Heart Failure with Reduced Ejection Fraction Aged 18 to 80 years Consented patients

Exclusion criteria:

Pregnancy Lactation Liver failure Renal failure (estimated glomerular filtration rate less than 30 ml/min) Patients with a history of taking dapagliflozin or empagliflozin Diabetes mellitus Contraindications of dapagliflozin or empagliflozin Inflammatory and autoimmune diseases Systolic blood pressure less than 100 or more than 180 mm Hg Symptomatic hypotension Malignancy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Arrangement of the randomization process: Determining each block size (quadruple blocks), Preparing the list of the blocks, and assigning a number to each of them AAB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6), Choosing random numbers between 1 and 6 by Excel software, Defining the treatment assignment list. For example: AAB(1)_BBAA(4)_ABAB(2)_BABA(5)

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind and none of the patients and researchers will know about the process of assigning patients to the intervention and placebo groups. For this

purpose, dapagliflozin, empagliflozin and placebo will be similarly packaged and given to the patient. Also, dapagliflozin, empagliflozin and placebo tablets will have the same shape, color, and size.

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

Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2023-09-11, 1402/06/20

Ethics committee reference number

IR.TBZMED.PHARMACY.REC.1402.024

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

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

2**Description of health condition studied**

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

New York Heart Association (NYHA) Functional Classification

Timepoint

At baseline and 40 days after intervention

Method of measurement

Assessment by one cardiologist

Secondary outcomes

1

Description

High-sensitivity C-reactive protein (hs-CRP)

Timepoint

At baseline and 40 days after intervention

Method of measurement

Laboratory test

2

Description

NT-proBNP

Timepoint

At baseline and 40 days after intervention

Method of measurement

Laboratory test

3

Description

Ejection fraction

Timepoint

At baseline and 40 days after intervention

Method of measurement

Echocardiography

4

Description

Left ventricular end-diastolic volume

Timepoint

At baseline and 40 days after intervention

Method of measurement

Echocardiography

5

Description

Hospitalization due to cardiovascular reasons

Timepoint

Within 40 days after intervention

Method of measurement

Interview

Intervention groups

1

Description

Intervention group: Patients will receive 10 mg

empagliflozin daily for 40 days in addition to usual treatments.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive 10 mg dapagliflozin daily for 40 days in addition to usual treatments.

Category

Treatment - Drugs

3

Description

Control group: Patients will receive a placebo daily for 40 days along with usual treatments.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center of Tabriz

Full name of responsible person

Dr. Taher Entezari-Maleki

Street address

Shahid Madani Heart Center, Daneshghah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

International Relations Office, No 2 Central Building,
Tabriz University of Medical Sciences, University
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5165665931

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research-vice@tbzmed.ac.ir

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

Taher Entezari-Maleki

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data of an article can be published after making patients unrecognized.

When the data will become available and for how long

After publishing of article until 6 months after publishing of the results

To whom data/document is available

Data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researchers who request data will be permitted only to do analysis according to ethics for scientific aims.

From where data/document is obtainable

Applicants can receive data by sending an E-mail to

address of tentezari@gmail.com and get response from Dr. Taher Entezari Maleki.

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

After contacting the corresponding author(Dr. Taher Entezari Maleki), data will be sent to the Tabriz Shahid Madani hospital ethics committee and after receiving permission, data will be sent to applicants.

Comments