Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 6695 4709

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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 AABB(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: AABB(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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5166614766
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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 Street
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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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Shahid Madani Center, Daneshghah Street,Tabriz

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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
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