Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Dapagliflozin effects in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention: a randomized clinical trial

Protocol summary

Study aim

Effects of dapagliflozin in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 100 patients. Randomization was performed using permuted block randomization method.

Settings and conduct

This is a double-blind randomized clinical trial on 100 patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention at Tabriz Shahid Madani Hospital. Patients in the intervention and control groups will receive dapagliflozin and placebo for 40 days. Patients will be compared regarding ST resolution, cardiac troponin I, high-sensitivity C-reactive protein level, ejection fraction, and major adverse cardiac events. Patients and researchers will not know about the assignment of patients to the intervention and placebo groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: STelevation myocardial infarction patients undergoing primary percutaneous coronary intervention, Ages 18-80 years, ability to understand and sign the consent form. Exclusion criteria: Pregnancy, Breastfeeding, Kidney failure (estimated glomerular filtration rate less than 30 ml/min), Liver failure, Systolic blood pressure below 100 mmHg, Inflammatory and autoimmune diseases, Diabetes mellitus, Chronic heart failure, Malignancy, Psychiatric disorders, Dapagliflozin contraindications, History of dapagliflozin use and myocardial infarction, symptoms onset more than 6 hours.

Intervention groups

The intervention group:patients will receive oral dapagliflozin of Modva Pharmaceuticals 10 mg/day for 40 days. The control group:patients will receive placebo of Modva Pharmaceuticals for 40 days plus standard treatments.

Main outcome variables

ST-segment resolution, Cardiac troponin I, hs-CRP, Ejection fraction, Major adverse cardiac events

General information

Reason for update

Adding the abbreviated name of the trial

Acronym

DAPA-STEMI

IRCT registration information

IRCT registration number: **IRCT20111206008307N44**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **1**

Registration date

2023-06-03, 1402/03/13

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

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dapagliflozin effects in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention: a randomized clinical trial

Public title

Dapagliflozin effects in patients with myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ST-elevation myocardial infarction undergoing primary percutaneous coronary intervention Patients aged between 18 to 80 years Consented patients

Exclusion criteria:

Pregnancy Lactation Renal failure (estimated glomerular filtration rate less than 30 ml/min) Hepatic failure Systolic blood pressure less than 100 mmHg Inflammatory and autoimmune diseases Diabetes mellitus Chronic heart failure Malignancy Psychiatric disorders Dapagliflozin contraindications History of receiving dapagliflozin History of myocardial infarction Arrival more than 6 hours from symptoms onset

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

Sample size

Target sample size: **100**

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 and placebo will be similarly packaged and given to the patient. Also, dapagliflozin 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

2023-04-17, 1402/01/28

Ethics committee reference number

IR.TBZMED.REC.1402.086

Health conditions studied

1

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

ST-segment resolution

Timepoint

Before intervention and 90 min after intervention

Method of measurement
Electrocardiogram

2

Description
Cardiac troponin I
Timepoint
before intervention and then every 6 hours for the first 24 hours after intervention and every 12 hours to 72 hours after intervention
Method of measurement
ELISA test

3

Description
High-sensitivity C-reactive protein (hs-CRP)
Timepoint
Before the intervention and 3 days after the intervention
Method of measurement
Immunoturbidimetry method

4

Description
Cardiac ejection fraction
Timepoint
Before the intervention and 40 days after the intervention
Method of measurement
Echocardiography

5

Description
Major adverse cardiac events
Timepoint
Within 40 days after Intervention
Method of measurement
Interview

6

Description
Quality of life
Timepoint
Before the intervention and 40 days after the intervention
Method of measurement
MacNew questionaire

Secondary outcomes

empty

Intervention groups

1

Description
The Intervention group will receive oral dapagliflozin of Modava pharmaceutical 10mg/day for 40 days in addition to usual treatments.
Category
Treatment - Drugs

2

Description
The Control group will receive oral placebo of Modava pharmaceutical daily for 40 days along with usual treatments.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Medical & Training Hospital
Full name of responsible person
Dr. Taher Entezari-Maleki
Street address
Shahid Madani Hospital, Daneshgah 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
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No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah 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?
No

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
دانشیار
Latest degree
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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 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