

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)

Phone

+98 21 6695 4709

Email address

tentezarimaleki@razi.tums.ac.ir

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 questionnaire

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3337 3901

Email

tentezari@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Email

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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Madani Center, Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3335 5983

Email

tentezari@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-Maleki

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3335 5983

Email

tentezari@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-Maleki

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Daneshghah Street

City

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Province

East Azarbaijan

Postal code

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Phone

+98 41 3335 5983

Email

tentezari@gmail.com

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