Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

To compare the carotid intima-media thickness in ultrasound of type II diabetic patients with myocardial infarction requiring primary angioplasty in two groups receiving empagliflozin and placebo.

Protocol summary

Study aim

To compare the carotid intima-media thickness in ultrasound of type II diabetic patients with myocardial infarction requiring primary angioplasty in two groups receiving empagliflozin and placebo.

Design

A randomized, double-blinded clinical trial with a parallel group design of 100 patients, randomized with randomizer software.

Settings and conduct

The double-blind clinical trial (researcher and patient) is parallel. The drugs are coded by the company and given to the patients by the cardiac department, and the radiology department is not involved in prescribing the drugs. The study patients will be randomly selected from type 2 diabetic patients with STEMI, along with the presence of ST-segment elevation above 0.1 mV in two or more leads in the ECG, who were admitted to Ayatollah Mousavi Hospital in Zanjan between August 1402 and September 1402 became. 80 patients are randomly divided into two groups of 40, intervention and control.All patients will be subjected to B-mode and Doppler ultrasound once before the administration of empagliflozin 10 mg/placebo tablets and again after the end of the follow-up period (3 months). All ultrasound examinations will be performed by a radiologist using the SuperSonic imagine ultrasound machine with the SL15-4 Linear probe. Carotid intima-media thickness is measured in the posterior wall of the common carotid artery and in the area without plaque.

Participants/Inclusion and exclusion criteria

inclusion: Type 2 diabetic patients with MI who were previously treated with oral glucose-reducing drugs and patients with STEMI exclusion: type 1 diabetes _ severe liver failure _ age under 18 years old _ advanced renal failure _ allergy to empagliflozin

Intervention groups

empagliflozin /placebo

Main outcome variables

carotid intima media thickness; resistance index of common carotid and internal carotid ; Atherosclerotic plaques

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230727058945N1**
Registration date: **2023-08-23, 1402/06/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-23, 1402/06/01**
Update count: **0**

Registration date

2023-08-23, 1402/06/01

Registrant information

Name

hadi sabat sani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 405 1359

Email address

hs742022@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-13, 1402/05/22

Expected recruitment end date

2023-09-13, 1402/06/22

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To compare the carotid intima-media thickness in ultrasound of type II diabetic patients with myocardial infarction requiring primary angioplasty in two groups receiving empagliflozin and placebo.

Public title
Empagliflozin in carotid intima-media thickness
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
type 2 diabetic patients with a history of glucose reducing medications patients with STEMI with ST-segment elevation more than 0.1mv in two or more leads in ECG
Exclusion criteria:
cardiogenic shock hypoglycemia diabetic ketoacidosis history of coronary artery bypass surgery type 1 diabetes severe liver failure advanced cancer patients history of allergy to Empagliflozin or ingredients severe renal failure, ESRD, or dialysis hypovolemia inflammatory diseases Cancer history advanced heart failure patients under 18 years of age pregnancy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Block randomization. By third-person coding, drug and placebo are divided into two groups, even and odd. With the random allocation rule method, a set of 40 even codes and 40 odd codes are obtained, which is recorded using the randomizer software, and based on that, the medicine is delivered to the patients. Randomization tool: Randomizer software
Blinding (investigator's opinion)
Double blinded
Blinding description
A person outside the research team labels the drug and placebo, which are both prepared by Abidi Pharmaceuticals, with labels A and B. Blocking of patients by randomizer software will be designed in 4 blocks and written on the sheets and will be chosen randomly by the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Science
Street address
N0.6, Block 4, Zaytoun Complex, 13 East Ave., Karmandan
City
Zanjan
Province
Zanjan
Postal code
1274659009
Approval date
2023-07-04, 1402/04/13
Ethics committee reference number
IR.ZUMS.REC.1402.100

Health conditions studied

1

Description of health condition studied
myocardial infarction
ICD-10 code
I21.3
ICD-10 code description
ST elevation (STEMI) myocardial infarction of unspecified site

2

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description
Carotid intima-media thickness

Timepoint
Measurement of intima media thickness of carotid artery at the beginning of the study (before the intervention) and 3 months after the start of drug use.
Method of measurement
B-mode and Doppler ultrasound

2

Description
Carotid resistivity index
Timepoint
Measurement of the carotid artery resistivity index at the beginning of the study (before the intervention) and 3 months after starting the drug.
Method of measurement
B-mode and Doppler ultrasound

3

Description
Atherosclerotic plaques
Timepoint
Measurement of atherosclerotic plaques at the beginning of the study (before the intervention) and 3 months after starting the drug.
Method of measurement
B-mode and Doppler ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this group, 40 type 2 diabetic patients treated with oral drugs, will recieve Empagliflozin from Abidi Pharmaceutical Company in the form of 10 mg tablets,once a day oally for 3 months.
Category
Treatment - Drugs

2

Description
Control group: in this group, 40 type 2 diabetic patients treated with oral drugs, will recieve Placbo made by Abidi Pharmaceutical Company ,once a day oally for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Hadi Sabat sani
Street address
Gavazang Blvd, in front of the University of Basic Sciences
City
Zanjan
Province
Zanjan
Postal code
5618345139
Phone
+98 24 3345 6006
Email
info@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abidi Pharmaceutical Company
Full name of responsible person
Seyed Amir Razavian Ardehali
Street address
No. 72, Abidi Blvd, Kilometer 8 of Shahid Lashkari Highway
City
Tehran
Province
Tehran
Postal code
1389776363
Phone
+98 21 4452 2451
Fax
+98 21 4450 4787
Email
hs742022@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Abidi Pharmaceutical Company
Proportion provided by this source
30
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
Industry

2

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Habib Zeighami
Street address
Professor Youssef Sobouti Blvd., Zanjan University of Medical Sciences, Faculty of Medicine
City
Zanjan
Province
Zanjan
Postal code
4513956111
Phone
+98 24 3314 0021
Email
Zeighami@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zanjan University of Medical Sciences

Proportion provided by this source
10

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
Zanjan University of Medical Sciences
Full name of responsible person
Hadi Sabat Sani
Position
MD, radiology resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
Street address
N0.6, Block 4, Zaytoun Complex, 13 East Ave., Karmandan
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

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