

# 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 receive Empagliflozin from Abidi Pharmaceutical Company in the form of 10 mg tablets, once a day orally for 3 months.

### **Category**

Treatment - Drugs

### **2**

### **Description**

Control group: in this group, 40 type 2 diabetic patients treated with oral drugs, will receive Placbo made by Abidi Pharmaceutical Company, once a day orally 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**City**

Zanjan

**Province**

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**Postal code**

1274659009

**Phone**

+98 44 3365 4571

**Email**

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**Person responsible for scientific 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

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**Person responsible for updating data****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**

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**Email**

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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