

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Evaluation of the effect of empagliflozin administration on reduction of cardiovascular complication in diabetic patients after PCI

#### Protocol summary

##### Study aim

Evaluation of the effect of empagliflozin administration on reduction of cardiovascular complication in diabetic patients after PCI

##### Design

This is a clinical trial study with parallel groups, double-blinded randomized, Phase 3, will be conducted on 100 patients with type 2 diabetes underwent percutaneous coronary intervention (PCI). Assignment of patients to the study groups will be done by random-numbers table and using computer.

##### Settings and conduct

This study will be performed on patients with type 2 diabetes underwent PCI referring to Golestan Hospital, Ahvaz. At least 100 patients will be randomly assigned to one of study groups. The patients, experimenters and data analyzer will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with definitive diagnosis of diabetes mellitus type 2 ( $HbA1c \geq 6.8\%$ ), consent to participate in the study; Exclusion criteria: Diabetic ketoacidosis, Urinary and genital infections, Type 1 diabetes, Severe liver failure, Existence of malignancy and cancer,  $eGFR 30 < ml/min$ .

##### Intervention groups

In the first group the patients will received empagliflozin (Abidi Pharmaceutical Company, Iran; 10 mg or once daily) in addition to standard of care for 6 months after percutaneous coronary intervention (PCI). The patients in the second group will received matching placebo, in addition to standard of care for 6 months after the PCI.

##### Main outcome variables

The incidence of major adverse cardiovascular events (MACE) such as non-fatal MI, all- cause mortality, acute myocardial infarction, cardiac death, in-stent thrombosis and unstable angina during 6 month follow up after treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210612051550N1**

Registration date: **2021-06-20, 1400/03/30**

Registration timing: **prospective**

Last update: **2021-06-20, 1400/03/30**

Update count: **0**

##### Registration date

2021-06-20, 1400/03/30

##### Registrant information

##### Name

Saad Fazeli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3001 3374

##### Email address

fazeli.s@ajums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-07-23, 1400/05/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of empagliflozin administration on reduction of cardiovascular complication in diabetic patients after PCI

**Public title**

The effect of empagliflozin on reduction of cardiovascular complication after PCI

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with definitive diagnosis of diabetes mellitus type 2 (HbA1c $\geq$  6.8%) Consent to participate in the study

**Exclusion criteria:**

Diabetic ketoacidosis Urinary and genital infections Type 1 diabetes Severe liver failure Existence of malignancy and cancer eGFR 30 < ml/min

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the treatment groups of empagliflozin or placebo after PCI procedure. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Intervention (receiving empagliflozin or placebo) and patient evaluation will be carried out by a physician who is blinded to treatment groups. Also patients and statistical analyzer will not know about patient grouping.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Golestan Hospital

**Street address**

Golestan Hospital, Faevardin Ave., Golestan Blvd.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733118

**Approval date**

2020-10-20, 1399/07/29

**Ethics committee reference number**

IR.AJUMS.HGOLESTAN.REC.1399.107

**Health conditions studied****1****Description of health condition studied**

Type 2 diabetes mellitus

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

**Primary outcomes****1****Description**

Major adverse cardiovascular events (MACE)

**Timepoint**

During 6 month follow up after PCI

**Method of measurement**

Based on symptoms and clinical examinations, laboratory parameters and echocardiographic assessment

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The patients will received empagliflozin (Abidi Pharmaceutical Company, Iran; 10 mg or once daily) in addition to standard of care for 6 months after percutaneous coronary intervention (PCI)

**Category**

Prevention

## 2

### Description

Control group: The patients will received matching placebo, in addition to standard of care for 6 months after the PCI.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golestan Hospital

##### Full name of responsible person

Seyed Mohammad Hassan Adel

##### Street address

Golestan Hospital, Faevardin Ave., Golestan Blvd.

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135733118

##### Phone

+98 61 3374 3001

##### Email

adel-smh@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badavi

##### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Blvd.

##### City

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##### Province

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##### Postal code

6135733118

##### Phone

+98 61 3373 8383

##### Email

badavim@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Saad Fazeli

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Cardiology

##### Street address

Ahvaz Jundishapur University of Medical Sciences,  
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##### Fax

##### Email

fazeli.s@ajums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Saad Fazeli

##### Position

Resident

##### Latest degree

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##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

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Ahvaz University of Medical Sciences

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**Position**

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**Fax**

**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