Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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≥ 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≥ 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
Khouzestan
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
Ahvaz
Province
Khouzestan
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, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3001 3374
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
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone

+98 61 3001 3374

Fax

Email

fazeli.s@ajums.ac.ir

Person responsible for updating data

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, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3001 3374

Fax

Email

fazeli.s@ajums.ac.ir

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