

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Empagliflozin on cardiac function in non- diabetic patients after primary percutaneous angioplasty on left anterior descending coronary artery

Protocol summary

Study aim

Efficacy of empagliflozin on cardiac function in non-diabetic patients after primary PCI on LAD

Design

two arms parallel groups design of 44 patients in each arm randomized trial with blinded receiving 10 mg empagliflozin daily tablet or placebo

Settings and conduct

trial is designed in Tehran Heart Center. patient and the first researcher are blind to give medication and data gathering. second researcher who monitors data gathering and giving medicine is not blind. in this trial, in first 48 hours of acute MI 10 mg Empagliflozin or placebo give to patient for 3 months. first 48 hours and after three months, echocardiography is done by an Echocardiologist and blood samples

Participants/Inclusion and exclusion criteria

Entry: non-diabetic patients with PPCI on LAD that are SVD: non-diabetic patients definition: 1-HbA1C<6.5 2-history of non-diabetes 3-twice FBS<100 if two of three of these exist patient is eligible for entry of trial. exclude: 1-History of serious hypersensitivity to empagliflozin or any component of the formulation; - Severe renal impairment (eGFR <30 mL/minute/1.73 m²), end-stage renal disease (ESRD), or dialysis 2-patients that have more than one vessel disease or have SVD with non-culprit lesion >70% or with SVD of LCX or RCA 3-patients 4- diabetic patients

Intervention groups

two groups and each person receive one tablet of 10 mg empagliflozin or placebo.

Main outcome variables

Determine decreasing of BNP in arm of receiving empagliflozin after three months and comparing with receiving placebo determine cardiac systolic and diastolic function after 3 months in two arms and comparing each other determine decreasing of BNP in

arm of receiving empagliflozin after 48 hours and comparing with arm of receiving placebo determine improvement of global longitudinal strain in arm of receiving empagliflozin after 48 hours and comparing with arm of receiving placebo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200727048226N1**

Registration date: **2020-08-06, 1399/05/16**

Registration timing: **prospective**

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Sara Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6582 9828

Email address

hosseini1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Empagliflozin on cardiac function in non-diabetic patients after primary percutaneous angioplasty on left anterior descending coronary artery

Public title

Efficacy of Empagliflozin on cardiac function in non-diabetic patients after primary percutaneous angioplasty on left anterior descending coronary artery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

non-diabetic patients with PPCI on LAD that are SVD:
non-diabetic patients definition: 1-HbA1C<6.5 2-history of non-diabetes 3-twice FBS<100 if two of three of these exist patient is eligible for entry of trial

Exclusion criteria:

1-History of serious hypersensitivity to empagliflozin or any component of the formulation; -Severe renal impairment (eGFR <30 mL/minute/1.73 m²), end-stage renal disease (ESRD), or dialysis 2-patients that have more than one vessel disease or have SVD with non-culprit lesion >70% or with SVD of LCX or RCA 3-patients 4- diabetic patients

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **88****Randomization (investigator's opinion)**

Randomized

Randomization description

this trial is a randomized double blind clinical trial with permuted block type of randomization. stratified randomization is done with statistical software.patients enter into blocks including four . and receiving placebo or empagliflozin randomizingly.first physician is blind about type of medication and second physician know the type of medication to find the probable side effect

Blinding (investigator's opinion)

Double blinded

Blinding description

patient and the first researcher are blind to give medication and data gathering. second researcher who monitors data gathering and giving medicine is not blind.

in this trial, in first 48 hours of acute MI 10 mg Empagliflozin or placebo give to patient for 3 months. in the first 48 hours , all of the followings are reviewed: 1- demographic data sheet, risk factors, history of cardiovascular diseases. 2- report of angiography is reviewed from PACS. 3- contraindication of receiving of medicine is reviewed. in 48 first 48 hours and after three months, echocardiography is done by an Echocardiologist and blood samples for FBS, CBC, BUN, Cr, BNP, HbA1C and lipid profile is given.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics of Tehran university of medical science

Street address

north karegar, tehran heart center

City

tehran

Province

Tehran

Postal code

1111111

Approval date

2020-07-30, 1399/05/09

Ethics committee reference number

22222

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

acute myocardial infarction

ICD-10 code

I21-09

ICD-10 code description**Primary outcomes****1****Description**

Efficacy of empagliflozin on cardiac function in non-diabetic patients admitted in Tehran Heart Center after primary PCI on LAD

Timepoint

echocardiography and blood sampling will be done 48 hours and after three months of receiving medicine

Method of measurement

three dimensional echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: each patient receives one 10 mg tablet of empagliflozin from abidi institute or placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

tehran heart center

Full name of responsible person

sara hosseini

Street address

north karegar

City

tehran

Province

Tehran

Postal code

11111111

Phone

+98 21 6582 9828

Email

hosseinisa1990@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

institute of researches of tehran university of medical science

Street address

north karegar

City

tehran

Province

Tehran

Postal code

11111111

Phone

+98 21 6582 9828

Email

hosseinisa1990@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

sara hosseini

Position

cardiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

north karegar

City

tehran

Province

Tehran

Postal code

11111111

Phone

00921865829828

Email

hosseinisa1990@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

sara hosseini

Position

resident of cardiology

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

north karegar

City

tehran

Province

Tehran
Postal code
1111111111
Phone
+98 21 6582 9828
Email
hosseinisa1990@gmail.com

hosseinisa1990@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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

some of the information are shared

When the data will become available and for how long

from 6 months after published

To whom data/document is available

for all researchers and scientists

Under which criteria data/document could be used

analysis in data is allowed

From where data/document is obtainable

hosseinisa@gmail.com

What processes are involved for a request to access data/document

in a week of request in email, receiving the answer

Comments

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
sara hosseini
Position
resident of cardiology
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
north karegar
City
tehran
Province
Tehran
Postal code
1111111111
Phone
+98 21 6582 9828
Email