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 recievieg 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 resercher 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, ehocardiography is done by an Echocardiologist and blood samples

Participants/Inclusion and exclusion criteria

Enery: 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 entery 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 recieve one tablet of 10 mg empagliflozin or placebo.

Main outcome variables

Determine decreasing of BNP in arm of reciveing empagliflozin afer three months and comparing with recieving placebo determine cardiac systolic and diastolic function after 3 months in two arms and comparing each other determine decreasing of BNP in arm of reciveing empagliflozin afer 48 thours and comparing with arm of receiving placebo determine improvement of global longitudinal srain in arm of reciveing empagliflozin afer 48 thours 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

hosseinisa1990@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 entery 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
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

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

Sample size
Target 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 recieving 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 resercher 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 recieving of medicine is reviewed. in 48 first 48 hours and after three months, ehocardiography 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
121-09
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 reciveing medicine
Method of measurement

three dimentional echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: each patient recieves 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
111111111
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
111111111
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

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

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 afer 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, recivivig the answer

Comments