Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of empagliflozin on diastolic function in prediabetic people with body mass index>30 kg/m2 Imam Hossein Hospital

Protocol summary

Study aim
Investigating the effects of empagliflozin on diastolic function of pre-diabetic patients with BMI above 30 kg/m2

Design
Clinical trial with control group, with parallel groups, phase 3, triple blind, randomized on 38 patients. 4 random blocks are used for randomization.

Settings and conduct
Pre-diabetic patients who referred to Imam Hossein hospital in 1401 are subjected to clinical and laboratory evaluations including lipid profile, FBS, 2hpp, HbA1C. Then the patients are randomly divided into intervention and control groups.They are subjected to transthoracic echocardiography to check cardiac diastolic function. Patients are then treated with empagliflozin 10 mg daily for three months. After three months, the patients will be re-evaluated . Patients will be monitored for drug side effects during the study. Empagliflozin drug of Actover Pharmaceutical Company (10 mg tablet in fasting form) and placebo (10 mg zinc sulfate tablet) with similar packaging, but different codes from the combination of numbers and letters A and B are used. Each patient is assigned a code at the beginning of the study, which is known by that code until the end of the study. This study is done as a three-way blind. In fact, both patients, doctors and laboratory personnel, outcome assessors and study data analysts are unaware of patient grouping.

Participants/Inclusion and exclusion criteria
inclusion criteria Age over 18 years; Diagnosis of pre-diabetes; BMI greater than or equal to 30 kg/m2; Stable cardiac symptoms for at least the last three months; Not receiving empagliflozin during the last 6 months

Intervention groups
After selection, based on the entry and exit criteria, the patients are placed in 2 groups using empagliflozin and placebo for a period of 3 months.

Main outcome variables
Early peak velocity/ Late peak Velocity (E/A)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220910055934N1**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-01, 1401/08/10**
Update count: **0**

Registration date
2022-11-01, 1401/08/10

Registrant information

Name
Reza Maleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7343 0000

Email address
maleki330@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of empagliflozin on diastolic function in prediabetic people with body mass index>30 kg/m2
Imam Hossein Hospital

Public title
Evaluation the effect of empagliflozin on diastolic function prediabetic people
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age more than 18 years old prediabetic (100<FBS<125) BMI more than 30 kg/m2 stability in cardiac symptom in the last 3 months
Exclusion criteria:
Using empagliflozin during the last 3 months
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **39**
Randomization (investigator's opinion)
Randomized
Randomization description
The 4 random blocks are used. Each label has a letter A or B and the random sequence method is created using the website www.sealedenvelope.com using the random block method of 4 based on treatment group A or B for 38 (two groups of 19) patients.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Empagliflozin drug of Actover Pharmaceutical Company (10 mg tablet in fasting form) and placebo (10 mg zinc sulfate tablet) with similar packaging, but different codes from the combination of numbers and letters A and B are used. Each patient is assigned a code at the beginning of the study, which is known by that code until the end of the study. This study is done as a three-way blind. In fact, both patients, doctors and laboratory personnel, outcome assessors and study data analysts are unaware of patient grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Madani Street
City
Tehran
Province
Tehran
Postal code
1617763141
Approval date
2022-10-18, 1401/07/26
Ethics committee reference number
IR.SBMU.MSP.REC.1401.317

Health conditions studied

1

Description of health condition studied
Diastolic dysfunction
ICD-10 code
I50.1
ICD-10 code description
Left ventricular failure

2

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

3

Description of health condition studied
pre-diabetic
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The effect of empagliflozin in improving the E/e ratio after 3 months treatment
Timepoint
E/e dosing before the start of the study and after 3 months of continuous drug use
Method of measurement
Echocardiography

2

Description
FBS
Timepoint
Before the intervention and 3 months after taking Empagliflozin
Method of measurement
Blood test

3

Description
the effect of Empagliflozin on blood pressure
Timepoint
Blood pressure measurement before the start of the study and after 3 months of continuous use
Method of measurement
Pressure gauge device

4

Description
The effect of empagliflozin on lowering blood sugar by measuring 2hpp
Timepoint
Blood sugar measurement using 2hpp before the intervention and 3 months after taking Empagliflozin
Method of measurement
blood test

5

Description
The effect of empagliflozin on lowering blood sugar by measuring HbA1c
Timepoint
Blood sugar measurement using HbA1C before the intervention and 3 months after taking Empagliflozin
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will be treated with Empagliflozin 10 mg of Actover pharmaceutical company daily for 3 months. Cardiac function will be measured by Philips echocardiography device before and after 3 months of treatment. Blood sugar and blood lipid profile will be measured by an accredited laboratory, as well as blood pressure and BMI at these two times.
Category
Treatment - Drugs

2

Description
The control group will be treated with placebo daily for 3 months. Cardiac function will be measured by Philips echocardiography device before and after 3 months of treatment. Blood sugar and blood lipid profile will be measured by an accredited laboratory, as well as blood pressure and BMI at these two times.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Roxana Sadeghi
Street address
Shahid Madani Street
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
info.rhmc@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Daneshjoo Blvd, Velenjak, St., Tehran.
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 9770
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roxana Sadeghi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Shahid Madani University
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
roxan.sadeghi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roxana Sadeghi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Madani Street, Imam Hossein Hospital
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
roxan.sadeghi@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Reza Maleki
Position
Cardiology resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Madani Street, Imam Hossein Hospital
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Fax
Email
maleki330@yahoo.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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
All researchers working in academic and scientific institutions, doctors and pharmaceutical companies will be allowed to access the information
Under which criteria data/document could be used
The applicant can access the information after providing proof of identity.
From where data/document is obtainable
Applicants can contact Dr. Reza Maleki at

maleki330@yahoo.com to receive the desired documents or data

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

The applicant can communicate with the researcher through e-mail and receive the basic data after presenting the identity documents

Comments