

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

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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

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Shahid Madani Street

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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.

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1983969411

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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

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Fax**Email**

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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