Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Empagliflozin on left ventricular volumes in type 2 diabetes or prediabetes patients with heart failure with reduced ejection fraction

Protocol summary

Study aim

1. Comparison of left ventricular end systolic volume (LVESV) before and after intervention in Empagliflozin and placebo groups 2. Comparison of left ventricular end diastolic volume (LVESV) before and after intervention in Empagliflozin and placebo groups 3. Comparison of left ventricular ejection fraction (LVEF) before and after intervention in Empagliflozin and placebo groups 4. Comparison of LVGLS before and after intervention in Empagliflozin and placebo groups 5. Comparison of cardiovascular complications in diabetic and pre-diabetic patients in Empagliflozin and placebo groups 6. Comparison of changes in left ventricular volumes in diabetic and pre-diabetic patients in two groups

Design

A double-blinded randomized clinical trial with placebo group, phase 3 on 112 patients. Randomization is performed using the permuted block randomization.

Settings and conduct

Emam Khomeini and Golestan hospitals, Ahvaz

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with type 2 diabetes mellitus (HbA1C≥ 6.5%) or pre-diabetes (HbA1c between 5.7% to 6.4%) and ischemic heart failure with reduced fractional ejection (LVEF ≤ 40%) 2. Age over 18 years 3. Functional NYHA Class II to IV 4. Patient consent to participate in the study Exclusion criteria: 5. Type 1 diabetes 6. Severe liver failure 7. History of diabetic ketoacidosis 8. Presence of any malignancy and cancer 9. Lack of adherence to the treatment regimen 10. eGFR < 30ml/min/1.73m2

Intervention groups

In the first group, Empagliflozin 10 mg is given once a day and in the second group, placebo. Patients are treated for 36 weeks. During the study, patients in both groups also receive standard HFrEF treatments.

Main outcome variables

In case of drug effects on the improvement of ventricular volume, fractional ejection and survival of patients, it can lead to a reduction in cardiovascular complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211219053450N1**
Registration date: **2022-06-05, 1401/03/15**
Registration timing: **prospective**

Last update: **2022-06-05, 1401/03/15**
Update count: **0**

Registration date

2022-06-05, 1401/03/15

Registrant information

Name

Omid Sherafat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3222 8037

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omidsherafat70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-16, 1401/04/25

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Empagliflozin on left ventricular volumes in type 2 diabetes or prediabetes patients with heart failure with reduced ejection fraction

Public title
Effect of Empagliflozin on left ventricular volumes in type 2 diabetes or prediabetes patients with heart failure with reduced ejection fraction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with type 2 diabetes mellitus (HbA1C≥ 6.5%) or pre-diabetes (HbA1c between 5.7% to 6.4%) and ischemic heart failure with reduced fractional ejection (LVEF ≤ 40%) over 18 years old Functional NYHA Class II to IV Patient consent for participation in research

Exclusion criteria:
Type 1 diabetes; Severe liver failure; eGFR <mL / min / 1.73m2 30; History of diabetic ketoacidosis; Existence of any malignancy and cancer; Lack of adherence to the treatment regimen.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into two groups of drugs and placebo. In this study, we will use the restricted randomization method of block randomization. The size of all the blocks is the same in both the drug and placebo groups, and we will have 4 blocks in this 2-group experiment. Randomization tool also uses random number tables.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is done in such a way that the person who randomizes and assigns people to groups has no information about the patients' condition and the study process. The patient and the person reviewing the results also did not know what group the people were in, and the study was conducted in a two-way blind.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research of Golestan Hospital, Ahvaz

Street address
Golestan street, Golestan hospital,Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2021-11-30, 1400/09/09

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.134

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50.9

ICD-10 code description
Heart failure, unspecified

Primary outcomes

1

Description
left ventricular volumes

Timepoint
before and 6 months after intervention

Method of measurement
Echocardiographic parameters

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Impagliflozin drug at a dose of 10 mg is administered once a day for 36 weeks.

Category
Treatment - Drugs

2

Description
Control group: Patients in the control group receive placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini hospital, Ahvaz
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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Deputy of research and technology
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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
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Ahvaz University of Medical Sciences
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Position
Resident
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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