

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Empagliflozin on clinical and echocardiographic parameters in non diabetic patient with reduced LVEF heart failure

Protocol summary

Study aim

The effectiveness of Empagliflozin on clinical and echocardiographic findings of patients with heart failure, in order to improve outcome

Design

A double blinded randomized controlled trial was conducted. This study was designed based on the principles of Helsinki and "GOOD CLINICAL PRACTICE" principles. The study was single - center; the subjects were randomly divided into two groups (i.e. 44 random number in excel to divide the coded people into intervention and control groups). The change in the LVEF was assessed; the sample size in each group is 22 and in total 44 people.

Settings and conduct

The drug and placebo were put in similar cans by a neutral person (other than the research members), called a and b. Participants will not be aware of either drug or placebo. The patients were randomly divided into two groups and control group. The study will be conducted on individuals of the heart clinic of Imam Hussain Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 80 years old; heart failure with EF less and equal 40 %; no history for diabetes.

Exclusion criteria: pregnancy or lactation; any history of diabetes, hospitalization due to cardiovascular event or renal disease over the last three months; GFR less than 45 mL / min / m²; systolic blood pressure less than 90 mmHg.

Intervention groups

Intervention group: Empagliflozin 10 mg will administer orally, daily for eight weeks. Control group: placebo is a medication that contains vitamin B1,100 mg, daily, for eight weeks .

Main outcome variables

The change of echocardiographic indicators and clinical indicators included quality of life, physical activity and clinical signs of heart failure after 8 weeks from the start

of consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210809052117N1**

Registration date: **2022-06-25, 1401/04/04**

Registration timing: **prospective**

Last update: **2022-06-25, 1401/04/04**

Update count: **0**

Registration date

2022-06-25, 1401/04/04

Registrant information

Name

Nasim Arabzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7746 0902

Email address

nasimarabbreeze@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-28, 1401/04/07

Expected recruitment end date

2022-07-18, 1401/04/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Empagliflozin on clinical and echocardiographic parameters in non diabetic patient with reduced LVEF heart failure

Public title

Effect of Empagliflozin on clinical and echocardiographic parameters in patient with reduced LVEF heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18 yr_80 yr Heart failure with reduced EF <40%
Nondiabetic Stable symptom and therapy for heart failure

Exclusion criteria:

Cardiovascular event, admission for cardiovascular or renal complications within last 3 months Cancer or life-threatening condition Estimated GFR < 45 ml/min/m2
Systolic blood pressure < 90mmhg Pregnancy or lactating women

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed by table number method, Odd numbers to case group and even numbers to control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study: placebo and empagliflozin were placed in two cans of same form and a color that named A , B. Participants and resercher, who include clinical care and outcome evaluator, did not know the nature of the contents of cans A , B .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Street, Yaman Ave., Velenjak, Chamran Highway

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Postal code

1985717443

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.SBMU.MSP.REC.1401.008

Health conditions studied

1

Description of health condition studied

Heart failre with reduced EF(ejection fraction)

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Echocardiography index

Timepoint

The beginning of the study and 8 weeks after start of empagliflozin

Method of measurement

Echocardiography

2

Description

Quality of life

Timepoint

The beginning of the study and 8 weeks after start of empagliflozin

Method of measurement

Kansas questionnaire

3

Description

Physical activity

Timepoint

The beginning of the study and 8 weeks after start of empagliflozin

Method of measurement

NYHA Class and 6-MWT

Secondary outcomes**1****Description**

Renal function

Timepoint

The beginning of the study and 8 weeks after start of empagliflozin

Method of measurement

Creatinine measuring and computing Glomerular Filtration Rate

2**Description**

Cardiac mortality

Timepoint

During the study

Method of measurement

Follow up

3**Description**

Myocardial Infarction

Timepoint

During the study

Method of measurement

Follow up

4**Description**

Duration of hospitalization for cardiac causes

Timepoint

During the study

Method of measurement

Follow up

Intervention groups**1****Description**

Intervention group: patient known case of heart failure, nondiabetic, 18_80yr with EF 40% or less and on standard HF treatment that confer to EMAM HOSSEIN cardiovascular Clinic; they receive empagliflozin 10 mg, daily

Category

Treatment - Drugs

2**Description**

Control group: patient known case of heart failure, nondiabetic, 18_80yr with EF 40% or less and on standard HF treatment that confer to EMAM HOSSEIN

cardiovascular Clinic, they receive vit B1 100 mg, daily

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Hosein hospital, Cardiovascular Clinic

Full name of responsible person

Nasim Arabzade

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Madani Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Velenjak, Chamran Blvd., Yaman Ave., Arabi Street

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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

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

Nasim Arabzadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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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

The data file of the participants , the study protocol , the statistical analysis map , consciously Consent form , the clinical study report , codes used in analysis , data classification system (data dictionary)

When the data will become available and for how long

Start the access period , 6 months after the results were published .

To whom data/document is available

It will only be available for researchers working in academic and academic institutions , or those involved in the industry can act to receive them .

Under which criteria data/document could be used

in order to conduct more research studies , such as multicenter of study and more complex analyses will be provided to other researchers .

From where data/document is obtainable

1.Tehran, madani street, Emam Hosein hospital, Dr Reza Miri, Dr Nasim Arabzade 2.No. 9, Shahid Saatchifar (4/36)

Ave, 5th street, Piroozi Blvd, Dr Nasim Arabzade.

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

Through submitting written request to the Teaching Vice

President of the Hospital Imam Hussein , Cardiovascular part

Comments