

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of different doses of empagliflozin on quality of life, heart function, atherosclerosis, vascular inflammation, blood pressure and lipid profile in non-diabetic patients with heart failure

Protocol summary

Study aim

Determining the effect of different doses of empagliflozin on quality of life, heart function, atherosclerosis, vascular inflammation, blood pressure and lipid profile in non-diabetic patients with heart failure

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 300 patients. To randomize the table of random numbers and use Sequentially numbered, sealed, opaque envelopes

Settings and conduct

This clinical trial will be performed in Professor Kojuri Cardiology clinic. major advanced cardiovascular event , side effect of medication , kcsq -12 quality of life score , NYHA functiona class, Ejectionfraction (EF), End-systolic dimention, six min walk test, Hba1c, Hematocrit(HCT), BMI, Urine analysis (U/A), Blood pressure(BP), Blood sugar (BS) , CRP-Hs, Cr / BUN, and their base level are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1) Patients with heart failure over eighteen years Exclusion criteria:1) Diabetic patients,2) Patients with an estimated glomerular filtration rate of less than 30 ml / min / 1.73 m2 (according to the diet modification in the kidney disease equation) in screening or implementation,

Intervention groups

After screening the patients by the researcher and having the conditions to enter and obtain informed consent by Concealed allocation method, a group consisting of 100 people is given 10 mg of empagliflozin every day for one year. A group of 100 people is given 25 mg of empagliflozin every day. One number is given for one year and a group of patients including 100 placebo is given one number every day for one year.major advanced cardiovascular event is considered as primary endpoint and will compare between groups.

Main outcome variables

Quality of life; Cardiac function; Atherosclerosis; Blood pressure; lipid profile; Blood sugar; Medication side effects; Heart failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210828052313N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Hossein Fatemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3636 1088

Email address

hoseinfatemian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-11-20, 1401/08/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of different doses of empagliflozin on quality of life, heart function, atherosclerosis, vascular inflammation, blood pressure and lipid profile in non-diabetic patients with heart failure

Public title
Empagliflozin in heart failure without diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 35<EF<50
Exclusion criteria:
 DM GFR<30

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
First, 300 people are selected from the eligible ones by Simple random sampling method and it is determined by the table of random numbers whether each person is in the treatment group or not. Then 300 envelopes with aluminum foil (in order not to clarify the contents of the envelopes) are prepared, and each of the random requests created is recorded on a card and the cards are placed inside the envelope. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface of the envelopes. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this clinical trial, neither participants nor researchers knew which treatment (which dose of empagliflozin) the participants were receiving by the end of the clinical trial.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shiraz University of Medical Sciences

Street address

Miraza shirazi blvd

City

Shiraz

Province

Fars

Postal code

7196878971

Approval date

2021-10-17, 1400/07/25

Ethics committee reference number

IR.SUMS.MED.REC.1400.372

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Ejection fraction

Timepoint

At the beginning of the study and 6 months after starting the drug

Method of measurement

Echocardiography

2

Description

Quality of life

Timepoint

At the beginning of the study and 6 months after starting the drug

Method of measurement

kansas city cardiomyopathy questionnaire

Secondary outcomes

1

Description

Laboratory finding

Timepoint

The beginning of the study and six months after starting the medication

Method of measurement

Laboratory measurement

Intervention groups

1

Description

Intervention group: A group of 150 people is given 10 mg of empagliflozin every night for one year

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Professor Kojuri cardiology clinic

Full name of responsible person

Hossein Fatemian

Street address

Nyayesh blvd

City

Shiraz

Province

Fars

Postal code

7196878971

Phone

+98 71 3654 0052

Email

hoseinfatemian@yahoo.com

Web page address

<https://www.kojurclinic.com/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

مهتاب معمارپور

Street address

Zand blvd

City

Shiraz

Province

Fars

Postal code

14336 71348

Phone

+98 71 3235 7282

Email

memarpour@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hossein Fatemian

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

Cardiology

Street address

Mirza Shirazi blvd

City

Shiraz

Province

Fars

Postal code

7196878971

Phone

+98 71 3636 1088

Email

hoseinfatemian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hossein Fatemian

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Raz building Golchin ave , kobar blvd , pol moaliabad town

City

Shiraz

Province

Fars

Postal code

7196878971

Phone

+98 71 3636 1088

Fax**Email**

hoseinfatemian@yahoo.com

Province

Fars

Postal code

7196878971

Phone

+98 71 3636 1088

Fax**Email**

hoseinfatemian@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Hossein Fatemian

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Raz building Golchin ave , kobar blvd , pol moaliabad town

City

Shiraz

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