Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of Empagliflozin as adjunctive therapy versus placebo on serum level of oxidative stress biomarkers in non-diabetic patients with systolic heart failure: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of Empagliflozin as adjunctive therapy versus placebo on serum level of oxidative stress biomarkers in non-diabetic patients with systolic heart failure

Design
This is a Phase III double-blind randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Farshchian Heart Hospital in Hamadan city, involving 80 eligible non-diabetic patients with systolic heart failure. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 80 years; Controlled systolic heart failure for at least 6 months; Hemoglobin A1c less than 6.5; Stable clinical and hemodynamic status. Exclusion criteria: Pregnancy or breastfeeding; Inflammatory, respiratory, infectious or malignant diseases; History of myocardial infarction, stroke, angioplasty or CABG in the last 3 months; Embedding pacemaker in the last 3 months; Use of anti-oxidant or anti-inflammatory drugs or corticosteroids in the last 3 months.

Intervention groups
Intervention group: Routine treatment plus Empagliflozin 10 mg tablet (manufactured by Abidi Pharmaceutical Co.) daily for 3 months. Control group: Routine treatment plus tablet placebo (manufactured by Abidi Pharmaceutical Co.) daily for 3 months

Main outcome variables
Serum levels of oxidative stress factors (malonaldehyde, superoxide dismutase, glutathione peroxidase), serum iron level, serum transferrin level, serum ferritin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N486**
Registration date: **2023-10-05, 1402/07/13**
Registration timing: **prospective**

Last update: **2023-10-05, 1402/07/13**
Update count: **0**

Registration date
2023-10-05, 1402/07/13

Registrant information

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Jalal Poorolajal

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Empagliflozin as adjunctive therapy versus placebo on serum level of oxidative stress biomarkers in non-diabetic patients with systolic heart failure: a double-blind randomized clinical trial

Public title

Effect of Empagliflozin as adjunctive therapy on serum level of oxidative stress biomarkers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 80 years Controlled systolic heart failure for at least 6 months Hemoglobin A1c less than 6.5 Stable clinical and hemodynamic status

Exclusion criteria:

Pregnancy or breastfeeding Inflammatory, respiratory, infectious or malignant diseases History of myocardial infarction, stroke, angioplasty or CABG in the last 3 months Embedding pacemaker in the last 3 months Use of anti-oxidant or anti-inflammatory drugs or corticosteroids in the last 3 months

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. The analyzer responsible for evaluating the trial's results will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a double-blind study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2023-09-09, 1402/06/18

Ethics committee reference number

IR.UMSHA.REC.1402.436

Health conditions studied

1

Description of health condition studied

Systolic heart failure

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

Primary outcomes

1

Description

Serum levels of oxidative stress factors (malonaldehyde, superoxide dismutase, glutathione peroxidase)

Timepoint

Before the intervention and 3 months later

Method of measurement
By blood sample testing

2

Description
Serum iron level
Timepoint
Before the intervention and 3 months later
Method of measurement
By blood sample testing

3

Description
Serum transferrin level
Timepoint
Before the intervention and 3 months later
Method of measurement
By blood sample testing

4

Description
Serum ferritin level
Timepoint
Before the intervention and 3 months later
Method of measurement
By blood sample testing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment plus tablet Empagliflozin 10 mg (manufactured by Abidi Pharmaceutical Co.) daily for 3 months
Category
Treatment - Drugs

2

Description
Control group: Routine treatment plus tablet placebo (manufactured by Abidi Pharmaceutical Co.) daily for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Heart Hospital in Hamadan city
Full name of responsible person
Dr. Maryam Mehrpooya
Street address
Farshchian Heart Hospital, Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Nariman Hama Saeed Mohammad
Position

Pharmacy Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

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Latest degree

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Other areas of specialty/work

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Professor of Epidemiology

Latest degree

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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