

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of Empagliflozin as adjunctive therapy versus placebo on serum level of oxidative stress biomarkers in 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 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 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 Type 2 diabetes 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 tablet Empagliflozin 10 mg (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

Primary outcome: Serum levels of oxidative stress factors (malonaldehyde, superoxide dismutase,

glutathione peroxidase), serum iron level, serum transferrin level, serum ferritin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N484**

Registration date: **2023-09-30, 1402/07/08**

Registration timing: **prospective**

Last update: **2023-09-30, 1402/07/08**

Update count: **0**

Registration date

2023-09-30, 1402/07/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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

Public title
Effect of Empagliflozin as adjunctive therapy versus placebo on serum level of oxidative stress biomarkers in diabetic patients with systolic heart failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 18 to 80 years Type 2 diabetes 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, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

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Position

Pharmacy Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

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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