

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation effect of empaglifulazin on depression in patients with heart failure with reduced ejection fraction: a randomized clinical trial

Protocol summary

Study aim

Evaluation effect of empaglifulazin on depression in patients with heart failure with reduced ejection fraction

Design

A controlled, parallel-group, blinded, phase 3 clinical trial of 50 patients.

Settings and conduct

This study is conducted as a randomized clinical trial on 50 patients over 18 years of age with heart failure with reduced ejection fraction who have referred to Shahid Madani Research and Treatment Center in Tabriz. The patients in the intervention groups will receive empagliflozin 25 mg and routine treatment. The patients in control group will receive empagliflozin 10 mg and routine treatment. Patients' depression will be evaluated and compared using the Hamilton grading scale at baseline and in months 1 and 3.

Participants/inclusion and exclusion criteria

Inclusion criteria: 1. Heart failure with reduced ejection fraction 2. Aged 18 to 80 years 3. Consented patients
Exclusion criteria: 1. History of using empagliflozin 2. Kidney failure 3. Symptomatic hypotension 4. Systolic pressure below 100 or above 180 mm Hg 5. Contraindications of empagliflozin 6. Liver failure 7. Pregnancy 8. Lactation 9. Malignancy

Intervention groups

Patients in intervention group will receive 25 mg empagliflozin daily in addition to the usual treatments. Patients in control group will receive 10 mg of empagliflozin daily for three months in addition to the usual treatments.

Main outcome variables

Hamilton grading scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N41**

Registration date: **2022-11-17, 1401/08/26**

Registration timing: **prospective**

Last update: **2022-11-17, 1401/08/26**

Update count: **0**

Registration date

2022-11-17, 1401/08/26

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

tentezarimaleki@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect of empaglifulazin on depression in patients with heart failure with reduced ejection fraction: a randomized clinical trial

Public title

Evaluation effect of empaglifulazin on depression in patients with heart failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Heart failure with reduced ejection fraction Aged 18 to 80 years Consented patients

Exclusion criteria:

History of using empagliflozin Kidney failure
Symptomatic hypotension Systolic pressure below 100 or above 180 mm Hg Contraindications of empagliflozin
Liver failure Pregnancy Lactation Malignancy

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using computer generated random number (systematic randomization) by online Graphpad software by determining 2 study groups and 25 patients in each group (Control and Intervention) by an independent person.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Reach etich committee of tabriz university of medical sciences

Street address

Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.TBZMED.REC.1401.461

Health conditions studied**1****Description of health condition studied**

Heart failure

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

Primary outcomes**1****Description**

Hamilton score chek list

Timepoint

Before intervention and 1, and 3 months after intervention

Method of measurement

Hamilton depression checklist

Secondary outcomes

empty

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

Intervention group: Patients will receive 25 mg of empagliflozin (Gloripa, Abidi Pharmaceutical Company) daily for three months in addition to the standard treatments for the treatment of heart failure with reduced ejection fraction.

Category

Treatment - Drugs

2**Description**

Control group: Patients will receive 10 mg empagliflozin (Gloripa, Abidi Pharmaceutical Company) daily for three months with standard treatments for the treatment of heart failure with reduced ejection fraction.

Category

Treatment - Drugs

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

Shahid Madani Heart Center

Full name of responsible person

Taher Entezari-Maleki

Street address

Shahid Madani Heart Center, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3337 3901

Fax

Email

tentezari@gmail.com

Position

Associated professor of clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Madani Center, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3335 5983

Email

tentezari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Golgasht, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3334 4280

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-Maleki

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-maleki

Position

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Other areas of specialty/work

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Street address

Shahid Madani Heart Center, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3335 5983

Fax

+98 41 1334 4798

Email

tentezari@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-Maleki

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Fax**Email**

tentezari@gmail.com

Web page address

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data of an article can be published after making patients unrecognized.

When the data will become available and for how long

After publishing of article until 6 months after publishing of the result

To whom data/document is available

Data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims.

From where data/document is obtainable

Applicants can receive data by sending an E-mail to address of tentezari@gmail.com and get response from Dr. Taher Entezari Maleki.

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

After contacting with corresponding author(Dr.Taher Entezari Maleki), data will be sent to Tabriz Shahid Madani hospital ethics committee and after receiving permission, data will be send to applicants.

Comments