

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation Effect of Empagliflozin and Colchicine on Quality of life in Heart Failure with Reduced Ejection Fraction: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation Effects of Coadministration of Empagliflozin and Colchicine on Quality of life in Heart Failure with Reduced Ejection Fraction with Using the KCCQ quality of life rating scale at baseline and in months 1and 3.

Design

Clinical trial with control group,not blind, randomized, phase 3, with a sample size of 96 patients. Randomization was performed using block randomization method by an independent person.

Settings and conduct

48 patients are randomly divided into two groups. Patients in the first group are treated with colchicine and empagliflozin , and the second group are treated with empagliflozin for 6 months. All patients will receive their standard treatment. After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. Colchicine and empagliflozin tablets and their placebo are identical in shape, color and size and are delivered to the patient in the package

Participants/Inclusion and exclusion criteria

Patients with a history of taking colchicine or empagliflozin, eGFR <30 mL/min/1.73 m², inflammatory and autoimmune diseases, symptomatic hypotension, systolic pressure below 100 or above 180 mm Hg, and other drug contraindications are excluded from the study. .

Intervention groups

In addition to the standard treatment, patients in the intervention group will also receive empagliflozin at a dose of 10 mg daily and colchicine at a dose of 1 mg daily for 3 months.

Main outcome variables

1. KCCQ grading scale
2. NYHA Functional Classification
3. Ejection fraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N40**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

Registration date

2022-11-05, 1401/08/14

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

2022-11-01, 1401/08/10

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Effect of Empagliflozin and Colchicine on Quality of life in Heart Failure with Reduced Ejection Fraction: A Randomized Clinical Trial

Public title

Effects of Coadministration of Empagliflozin and Colchicine on Heart Failure.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Heart Failure with Reduced Ejection Fraction Aged 18 to 80 years Consented patients

Exclusion criteria:

Pregnancy Lactation Liver failure Kidney failure Systolic blood pressure less than 100 or more than 180 mm Hg Diabetes mellitus 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

The patients are randomly divided into 2 groups of 25 people by the numbers obtained from the computer, and none of the people will be informed about the randomization samples and the interpretation process.

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

Ethics Committee of Tabriz University of Medical Sciences.

Street address

Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.TBZMED.REC.1401.096

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

Quality of life score in KCCQ questionnaire.

Timepoint

The beginning of the study and months 3 and 6

Method of measurement

KCCQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive 25 mg of empagliflozin daily for three months with standard treatments

Category

Treatment - Drugs

2

Description

Control group: Patients will receive 10 mg empagliflozin daily for three months with standard treatments

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center of Tabriz

Full name of responsible person

Dr. Taher Entezari-Maleki

Street address

Shahid Madani Heart Center, Daneshghah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

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

Tabriz University of Medical Sciences

Position

Taher Entezari-Maleki

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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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

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 results

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