Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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+98 21 6695 4709
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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

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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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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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