

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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 m<sup>2</sup>, 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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**Postal code**

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**Phone**

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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**

Tabriz, Daneshghah Street, Golgasht

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335710

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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 scientific inquiries

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Associated professor of Clinical pharmacy

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Email**

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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**