

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation Effects of Colchicine and Empagliflozin in with Reduced Ejection Fraction following MI: A Randomized Double-blind Placebo-controlled Trial

Protocol summary

Study aim

Evaluation Effects of Colchicine and Empagliflozin in Reduced Ejection Fraction following MI

Design

Clinical trial with control group, with parallel group design, 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

This is a randomized clinical trial on a total of 96 patients over 18 years with heart failure with reduced ejection fraction who attended the Shahid Madani clinic of Tabriz University of Medical Science. Patients in 2 intervention and one control groups will receive empagliflozin and colchicine. Patients will be compared regarding serum level of hs-CRP, NYHA Functional Classification, serum level of TNF alpha, and ejection fraction in three groups using SPSS by appropriate statistical tests (before starting treatment and one month later and three months later).

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. Pregnancy 2. Lactation 3. Liver failure 4. Kidney failure 5. Contraindications of colchicine or empagliflozin 6. Systolic blood pressure less than 100 or more than 180 mm Hg 7. Symptomatic hypotension 8. Autoinflammatory diseases 9. Malignancy 10. Diabetes mellitus

Intervention groups

In intervention group 1, patients will receive 25 mg of empagliflozin daily for three months with standard treatments. In intervention group 2, patients will receive 1 mg of colchicine and 10 mg of empagliflozin daily for three months with standard treatments. In control group, Patients will receive 10 mg empagliflozin daily for three months with standard treatments.

Main outcome variables

1. hs-CRP
2. NYHA Functional Classification
3. TNF alpha
4. Ejection fraction

General information

Reason for update

Considering that the study will start on 2 February 9, 2023, the approximate start time of the study was changed. Considering that the classification of the New York Heart Association, which is a subjective finding, will be used to evaluate patients' heart failure, the blinding process of participants and health-care providers have been explained.

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N39**
Registration date: **2022-10-27, 1401/08/05**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **3**

Registration date

2022-10-27, 1401/08/05

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

2023-02-09, 1401/11/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Effects of Colchicine and Empagliflozin in with Reduced Ejection Fraction following MI: A Randomized Double-blind Placebo-controlled Trial

Public title

Effects of Colchicine and Empagliflozin in Myocardial Dysfunction

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
Contraindications of colchicine or empagliflozin Systolic blood pressure less than 100 or more than 180 mm Hg
Symptomatic hypotension Autoinflammatory diseases
Malignancy Diabetes mellitus

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be carried out using random allocation site (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) by blocked randomization method with random block size 6 and 9.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and health care providers are not aware of the type of grouping of patients, and the study drug will be unrecognizable to patients and related treatment staff. A matched placebo is identical to colchicine in every aspect, such as appearance, smell, and taste. The only person who will know the type of drug is the

coordinator of the study.

Placebo

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

2022-07-30, 1401/05/08

Ethics committee reference number

IR.TBZMED.REC.1401.370

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

2

Description of health condition studied

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

High-sensitivity C-reactive protein (hs-CRP)

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Laboratory test

2

Description
New York Heart Association (NYHA) Functional Classification

Timepoint
At baseline and 1, and 3 months after intervention

Method of measurement
Assessment by one cardiologist

Secondary outcomes

1

Description
Left ventricular diastolic function

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Echocardiography

2

Description
Left ventricular end-diastolic diameter

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Echocardiography

3

Description
Mitral valve regurgitation grade

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Echocardiography

4

Description
Tumour Necrosis Factor alpha (TNF alpha)

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Laboratory test

5

Description
Ejection fraction

Timepoint

Before intervention and 1, and 3 months after intervention

Method of measurement
Echocardiography

6

Description
Total antioxidant capacity

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Laboratory test

7

Description
Malondialdehyde

Timepoint
Before intervention and 1, and 3 months after intervention

Method of measurement
Laboratory test

8

Description
Empagliflozin serum concentration

Timepoint
One and three months after intervention

Method of measurement
Laboratory test

9

Description
Left ventricular diastolic function

Timepoint
One and three months after intervention

Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group 1: Patients will receive 25 mg of empagliflozin daily for three months with standard treatments

Category
Treatment - Drugs

2

Description
Intervention group 2: Patients will receive 1 mg of colchicine and 10 mg of empagliflozin daily for three months with standard treatments.

Category
Treatment - Drugs

3

Description

Control group: 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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5166614766

Phone

+98 41 3337 3901

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

Tabriz, Daneshghah Street, Golgasht

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Tabriz

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East Azarbaijan

Postal code

335710

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

Position

Associated professor of Clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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