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

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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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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
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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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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