Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the outcomes of major adverse cardiac events after six-month colchicine consumption in the patients with ST-elevation myocardial infarction that underwent primary percutaneous coronary intervention.

Protocol summary

Study aim
Determining the outcome of six months of colchicine consumption, in terms of major adverse cardiac events, in patients with ST-elevation myocardial infarction, who underwent percutaneous coronary intervention

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 103 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Initial screening, diagnostic assessments, and prescription of either Colchicine or a placebo occurred on the first day of disease diagnosis for patients. A written informed consent form was given to each patient. Following their initial discharge, patients were scheduled for a clinic visit one week later. Subsequently, patients had monthly visits to the clinic for six months, during which their medication adherence, treatment effectiveness, and major adverse cardiac events were monitored. To ensure greater confidence in the results, all patients underwent evaluation every two months by two cardiologists, who reviewed them based on disease grouping and occurrence of major adverse events.

Participants/Inclusion and exclusion criteria
The exclusion criteria were as follows: 1) hepatic dysfunction; 2) moderate renal dysfunction (glomerular filtration rate less than 50); 3) leukemia; 4) thrombocytopenia; 5) long-term consumption of colchicine; 6) hypersensitivity to colchicine; 7) pregnancy or lactation; 8) left ventricular ejection fraction ˂30% prior surgical revascularization.

Intervention groups
1- Patients who had experienced ST-elevation myocardial infarction (STEMI), who were treated with colchicine in addition to conventional treatment. 2- Patients with STEMI who received placebo in addition to conventional treatment.

Main outcome variables
major adverse cardiac events (MACE)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230801059005N1**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date
2023-08-21, 1402/05/30

Registrant information
Name
Aida Bazrgar
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-09-23, 1402/07/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the outcomes of major adverse cardiac events after six-month colchicine consumption in the patients with ST-elevation myocardial infarction that underwent primary percutaneous coronary intervention.

Public title

Colchicine effects on Major Adverse Cardiac Events in patients who underwent PCI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who had experienced ST-elevation myocardial infarction (STEMI) In angiography of patients, in at least one of the epicardial arteries larger than or equal to two and a half millimeters, there should be a stenosis equal to or greater than fifty percent, which has been managed through percutaneous coronary intervention and medical therapy. patients were undergoing percutaneous coronary intervention (PCI).

Exclusion criteria:

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Screening, randomization, and administration of colchicine or placebo to patients are performed on the first day of disease diagnosis. Each patient, for entry into the study, reads an informed consent form and declares their willingness or unwillingness to participate in the research. Patients are randomly divided into two equal groups. In the intervention group, in addition to standard treatment for myocardial infarction with ST-segment elevation, colchicine is administered orally (tablet) at a daily dose of 0.5 milligrams (half in the morning, half at night). In the control group, in addition to the mentioned standard treatment, placebo is administered, which is packaged, colored, and sized similarly to colchicine. After discharge, the patients' first follow-up is conducted one week later through a clinic visit. Subsequently, patients are visited monthly for six months in the clinic, and their drug tolerance, adherence to prescribed treatment, and major adverse cardiac events are monitored. To ensure greater confidence, all patients are assessed every two months by two cardiologists who are unaware of patient grouping, for major adverse cardiac events.

Blinding (investigator's opinion)

Double blinded

Blinding description

To ensure fairness and reduce bias, we utilized a computer-based program with a block randomization protocol, and the block size factor was determined by the study investigators. Independent packaging personnel, not involved in the rest of the study, prepared the medication packages. All investigators, patients, and follow-up team members were kept unaware of the treatment assignments throughout the study, ensuring a non-biased controlled study. However, the blinding was broken in exceptional cases where knowledge of treatment allocation was necessary to manage seriously ill patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

zand Blvd, shiraz

City

shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-02-19, 1401/11/30

Ethics committee reference number

IR.SUMS.MED.REC.1402.001

Health conditions studied

1

Description of health condition studied

ST-elevation myocardial infarction

ICD-10 code

I21

ICD-10 code description

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

Primary outcomes

1

Description
major adverse cardiac events
Timepoint
at the beginning- 3 month- 6month
Method of measurement
questionnaire- angiography

Secondary outcomes

1

Description
myocardial infarctions, chest pain, resuscitated cardiac arrests, cardiovascular-related deaths, and strokes
Timepoint
at the beginning- 3 month- 6 month
Method of measurement
medical records- questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to standard treatment for myocardial infarction with ST-segment elevation, colchicine is administered orally (tablet) at a daily dose of 0.5 milligrams (half in the morning, half at night).
Category
Treatment - Drugs

2

Description
Control group: In the control group, in addition to the mentioned standard treatment, placebo is administered, which is packaged, colored, and sized similarly to colchicine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Heart Hospital
Full name of responsible person
Aida Bazrgar
Street address
No. 109, Alley 17, Esteghlal Blvd, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempur
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Fars Province, Shiraz, Zand
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Ali Safari
Position
fellowship student
Latest degree
Specialist
Other areas of specialty/work
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Position
Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only a part of data like primary outcome can be shared.
When the data will become available and for how long
The access period starts 1 year after the publication time of results
To whom data/document is available
This data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
The data will be made available to researchers for further studies or more advanced analysis.
From where data/document is obtainable
Researchers can send an email regarding the request for the data of our study to Dr. Hamed Bazrafshan. Email: Hamedbazrafshan@yahoo.com
What processes are involved for a request to access data/document
The researchers can request for this study's data through an e-mail one year after the publication data of this study in one of the pee-reviewed journals.
Comments