

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of colchicine on reperfusion arrhythmias in ST-elevation myocardial infarction (STEMI) patients treated with Primary Percutaneous Coronary Intervention (PPCI)

Protocol summary

Study aim

Investigating the effect of colchicine on arrhythmia reperfusion in acute myocardial infarction patients undergoing Primary Percutaneous Coronary Intervention (PPCI)

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized using random numbers, the intended sample size in two intervention and control groups is a total of 154 people.

Settings and conduct

Patients with STEMI referred to Bo Ali Qazvin Hospital who are candidates for PPCI are included in the study. Colchicine is administered to the intervention group before PPCI and placebo to the control group. The administration of colchicine will be in such a way that PPCI candidate patients will receive 2 grams of colchicine as STAT before PCI, and 0.5 mg of colchicine will be prescribed every twelve hours from the second day for 5 days.

Participants/Inclusion and exclusion criteria

All patients with STEMI who are candidates for PPCI

Intervention groups

Intervention group: people receiving colchicine Control group: people receiving placebo

Main outcome variables

- Angiographic findings of PPCI include initial and final TIMI of the involved vessel - The occurrence or non-occurrence of arrhythmia after reperfusion and the type of reperfusion arrhythmia if it occurs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220723055534N1**

Registration date: **2023-04-12, 1402/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-12, 1402/01/23**

Update count: **0**

Registration date

2023-04-12, 1402/01/23

Registrant information

Name

Seyed Amir Reza Mohajeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-27, 1401/06/05

Expected recruitment end date

2023-08-27, 1402/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of colchicine on reperfusion arrhythmias in ST-elevation myocardial infarction (STEMI) patients treated with Primary Percutaneous Coronary Intervention (PPCI)

Public title

Colchicine in myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with STEMI that are candidates for PPCI
Exclusion criteria:
Patients who previously used Colchicine or Prednisolone for any reason
Contraindications of Colchicine, including sensitivity to Colchicine, kidney failure (GFR < 10), liver failure (AST - ALT above 5 times normal) and definite history of serious liver diseases (such as hepatitis, hemochromatosis, Wilson's disease, cirrhosis) Drugs that interact with risk X with colchicine

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **154**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into 2 groups. The division of people between two groups will be in a double-blind manner, and the type of randomization will be by Block randomization method, after the exit of people with exclusion criteria. The method of performing randomization is in such a way that at first, the number of samples will be given to the Random Allocation Software version 1.0.0. In the next step, it will be determined that each number will be placed in which study group, and the main drug or placebo will be placed in the drug package of that code. When patients admitted to the medical center, drug packages are prescribed for them in the order of number.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the following people are blinded to the study groups: - Patients included in the study - Nurses who give colchicine or placebo to patients. - Cardiologist who performs PPCI for patients and report angiography results. - Nurses and researchers who evaluate the incidence of arrhythmia in patients. Considering that the packaging of medicines and numbering on the medicine packages will be done by other people and all the medicine packages are similar, none of the groups mentioned above have any knowledge of the type of medicine prescribed for the patient. . In the data analysis stage, the code of drug packages and their contents will be entered in the database file and the analysis will be done based on the type of drug.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin
City
Qazvin
Province
Qazvin
Postal code
5981134197

Approval date
2022-07-02, 1401/04/11

Ethics committee reference number
IR.QUMS.REC.1401.102

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

2

Description of health condition studied
Cardiac arrhythmia

ICD-10 code
I49

ICD-10 code description
Other cardiac arrhythmias

Primary outcomes

1

Description
The incidence of cardiac arrhythmia

Timepoint
The first day after the occurrence of STEMI

Method of measurement
Checking the rhythm recorded in the 24-hour monitor of

the patient

2

Description

Cardiac arrhythmia type in the first 24 hours after PPCI

Timepoint

The first day after the occurrence of STEMI

Method of measurement

Checking the rhythm recorded in the 24-hour monitor of the patient

3

Description

Comparison of initial and final TIMI of involved vessels

Timepoint

At the beginning and end of coronary angiography

Method of measurement

Based on the standard specified in Branwald's cardiology book, the division is done

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: STEMI patients who are candidates for PPCI, before PCI, receive 2 grams of colchicine as STAT, and from the second day, 0.5 mg of colchicine will be prescribed every twelve hours for 5 days.

Category

Treatment - Drugs

2

Description

Control group: These patients are candidates for PPCI, but they will receive placebo instead of colchicine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali Hospital

Full name of responsible person

Majid Hajikarimi

Street address

Buali Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahdi Mirhashemi

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first branch, Maudet Alley, Shahid Beheshti Blvd.

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Majid Hajikarimi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The entire data of this study will be shared based on the request of the journal in which the article of this study will be published after de-identifying the individuals.

When the data will become available and for how long

After publishing the results and printing the article

To whom data/document is available

All people who need the data of this study

Under which criteria data/document could be used

From where data/document is obtainable

Seyed Amir Reza Mohajeri a.mohajeri@qums.ac.ir
s.a.r.mohajery@gmail.com Majid Hajikarimi
majidhajikarimi57@gmail.com

What processes are involved for a request to access data/document

After receiving the applicant's request, this request will be submitted to the research assistant of Qazvin University of Medical Sciences, and if approved by this assistant, the information will be sent. This process will take about 2 weeks to a month.

Comments