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

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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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s.a.r.mohajery@gmail.com

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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Qazvin
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researchdpt@qums.ac.ir
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
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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