

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the low dose colchicine on the clinical outcome of patient with ST elevation myocardial infarction

#### Protocol summary

##### Study aim

Evaluation of the low dose colchicine on the clinical outcome of patient with ST elevation myocardial infarction.

##### Design

This study will be conducted as a double-blind clinical trial in two intervention and control groups with block randomization. In each group, 90 patients will be included in the study. The subject of intervention in this study is the drug colchicine with a dose of 0.5 mg, which is prescribed for patients in the intervention group, and placebo will be prescribed for patients in the control group. All patients will meet the study entry criteria.

##### Settings and conduct

This study will be conducted during the years 1401 and 1402 in the CCU and post-CCU departments of Shahid Beheshti Hospital, Qom. In order to observe blinding, the researcher and the examiner (evaluator of the patients during the follow-up period) will be unaware of the type of treatment group of the patients. After randomization, each patient will receive colchicine or placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age range from 18 to 80 years 2. Occurrence of STE in the patient's ECG. Exclusion Criteria: 1. Unstable vital signs of patients 2. Known drug sensitivity to colchicine 3. Severe liver and kidney disease 4. Chronic treatment with colchicine

##### Intervention groups

The intervention in this study is colchicine with a dose of 0.5 mg, which is prescribed for the patients of the intervention group, and the placebo drug, which is similar to colchicine in terms of color, size and packaging, will be prescribed for the patients of the control group.

##### Main outcome variables

Functional class of the patient until the occurrence of chest pain, need for re-hospitalization, mortality rate of patients, information obtained from echocardiography of patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231001059578N1**

Registration date: **2023-10-21, 1402/07/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-21, 1402/07/29**

Update count: **0**

##### Registration date

2023-10-21, 1402/07/29

##### Registrant information

##### Name

Ali Khosrobeigi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3612 2000

##### Email address

ali.khosrobeigi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-03, 1402/07/11

##### Expected recruitment end date

2024-01-31, 1402/11/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the low dose colchicine on the clinical outcome of patient with ST elevation myocardial infarction

#### Public title

Evaluation of the colchicine on the myocardial infarction

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

18 to 80 years old patient Occurrence of STE in the patient's ECG

##### Exclusion criteria:

Unstable vital signs of patients Known drug sensitivity to colchicine Severe liver and kidney disease Chronic treatment with colchicine

#### Age

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

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: **180**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

A lottery method will be used to assign patients to two intervention and control groups. In the first stage, the groups are written in the form of group A, B. Then, a lottery is drawn between the two groups to determine which is the intervention group and which is the control group. In the second step, the numbers of two cards written on one A and the other B and completely closed and not visible are thrown into a container. In the third stage, after obtaining consent from the patients and agreeing to participate in the study, they are asked to choose one of the two cards in the container in order to determine the treatment group. Then he takes a card from inside the container and hands it to the nurse. The nurse writes down the treatment group and the patient's medicine is prescribed according to the group it belongs to. This work will continue until 90 people in both groups are completed.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In order to observe blinding, the researcher and the patient will be unaware of the type of treatment group of the patients. The intervention in this study is colchicine with a dose of 0.5 mg, which is prescribed for the patients of the intervention group, and the placebo drug, which is similar to colchicine in terms of color, size and packaging, will be prescribed for the patients of the control group. Labeling, blinding, packaging of drugs and delivery of drugs to patients will be done by a person not familiar with the study (ward head).

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Qom University of Medical Sciences

##### Street address

Shahid Lavasani St. (Saheli) - Qom University of Medical Sciences - Qom

##### City

Qom

##### Province

Ghoum

##### Postal code

3713649373

#### Approval date

2023-01-30, 1401/11/10

#### Ethics committee reference number

IR.MUQ.REC.1401.235

## Health conditions studied

### 1

#### Description of health condition studied

myocardial infarction

#### ICD-10 code

I21

#### ICD-10 code description

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

## Primary outcomes

### 1

#### Description

the functional class of the patient until the occurrence of chest pain

#### Timepoint

At the beginning of the study, the first day, when the patients were discharged and after 40 days from intervention

#### Method of measurement

check list

## Secondary outcomes

empty

## Intervention groups

1

### Description

An oral loading dose of 2 mg equivalent to 2 colchicine (from Mofid Pharma Pharmaceutical Company) tablets will be given to the patients, followed by 0.5 mg once a day orally for 30 days.

### Category

Treatment - Drugs

2

### Description

Control group: Placebo (from Mofid Pharma Pharmaceutical Company) medicine, which is similar to colchicine in terms of color, size and packaging, will be prescribed for control group patients.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Beheshti Hospital, Qom

#### Full name of responsible person

Ali Khosrobeigi

#### Street address

Shahid Beheshti Hospital, Qom

#### City

qom

#### Province

Ghous

#### Postal code

3719964797

#### Phone

+98 25 3612 2000

#### Email

ali.khosrobeigi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ghous University of Medical Sciences

#### Full name of responsible person

ali khosrobeigi

#### Street address

Shahid Beheshti Street, Shahid Beheshti Hospital,  
Qom

#### City

qom

#### Province

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#### Postal code

3713649373

#### Phone

+98 25 3612 2000

#### Email

ali.khosrobeigi@gmail.com

### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ghous 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

Ghous University of Medical Sciences

#### Full name of responsible person

Ali khosrobeigi

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Cardiology

#### Street address

shahid beheshti hospital Qom

#### City

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ghous University of Medical Sciences

#### Full name of responsible person

Ali khosrobeigi

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Ghousm University of Medical Sciences  
**Full name of responsible person**  
Ali Khosrobeigi  
**Position**  
Resident  
**Latest degree**  
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**Other areas of specialty/work**  
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**Fax**

**Email**  
ali.khosrobeigi@gmail.com

## 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

All data is potentially shareable after de-identifying individuals

### When the data will become available and for how long

from 2024

### To whom data/document is available

all people

### Under which criteria data/document could be used

If the data and documents of this study are needed to conduct larger studies, the administrators of this study will provide all the data to the administrators of other studies.

### From where data/document is obtainable

dr khosrobeigi, ali.khosrobeigi@gmail.com

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

ali.khosrobeigi@gmail.com

### Comments