

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

Ghous

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

Ghous

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

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3612 2000

Email

ali.khosrobeigi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

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resident

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Cardiology
Street address
shahid beheshti hospital Qom
City
qom
Province
Ghousm
Postal code
3713649373
Phone
+98 25 3612 2000
Email
ali.khosrobeigi@gmail.com

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
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Shahid beheshti hospital, shahid beheshti street qom
City
Qom
Province
Ghousm
Postal code
3713649373
Phone
+98 25 3612 2000
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