Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of colchicine on reducing myocardial injury caused by coronary angioplasty procedure in patients with coronary artery disease

Protocol summary

Study aim
Determining the effect of Colchicine on reducing myocardial damage caused by coronary angioplasty procedure in patients with coronary artery disease referred to Shahid Madani Hospital in Khorramabad in 2023

Design
This study is a clinical trial study with a control group with parallel double-blind phase 3 groups on 210 patients. After the randomization, the patients will be divided into two intervention and control groups.

Settings and conduct
The study population is patients with angina pectoris who are candidates for coronary angiography, referring to Shahid Madani Hospital in Khorramabad.The study is double-blind.The participating patients and the doctor are blinded. In the intervention group, patients are treated with three doses of drugs. Colchicine is given before and after the procedure. Also, in the control group, three doses of placebo will be given in the same order. In both groups. The amount of troponin will be measured before the procedure and also 24 hours after the procedure with a quantitative troponin kit.

Participants/Inclusion and exclusion criteria
The most important criterion for entering is: stable and unstable angina pectoris and non-ST segment elevation myocardial infarction diagnosed by a cardiologist and candidate for coronary angiography. Inclusion criteria: having sensitivity to colchicine and not being a candidate for angioplasty after angiography and glomerular filtration below 30 ml/min.

Intervention groups
In the intervention group, patients will first receive 1 mg of colchicine 12 to 24 hours before the study and half a mg one hour later. They will also receive half a milligram of colchicine half an hour after the procedure. Patients in the control group will receive the same placebo drug as the intervention group

Main outcome variables
Troponin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231015059731N1**
Registration date: **2023-11-27, 1402/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-27, 1402/09/06**
Update count: **0**

Registration date
2023-11-27, 1402/09/06

Registrant information

Name
Zohre Taheri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3322 9222

Email address
dr.taheri96@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of colchicine on reducing myocardial injury caused by coronary angioplasty procedure in patients with coronary artery disease

Public title
The effect of colchicine on reducing myocardial injury

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from stable and unstable angina pectoris and myocardial infarction without ST segment elevation diagnosed by a cardiologist and a candidate for coronary angiography Not taking colchicine due to other diseases such as gout Not having a history of myelodysplasia Not taking corticosteroids or non-steroidal anti-inflammatory drugs except aspirin for 3 days before Absence of malignancy or active infection

Exclusion criteria:
Being allergic to colchicine Not being a candidate for angioplasty after angiography Glomerular filtration below 30 ml/min

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **210**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples in groups is done using block randomization method and patients are placed in 2 study groups in a balanced way by block randomization method.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients in both intervention and control groups have no information regarding receiving or not receiving placebo. Also, the doctor of Intervention has no information regarding which study group the patient undergoing angioplasty is in.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Second floor, technical office, Lorestan University of Medical Sciences, Anoushirvan Rezaei Square, Khorramabad city

City
Khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2023-10-15, 1402/07/23

Ethics committee reference number
IR.LUMS.REC.1402.229

Health conditions studied

1

Description of health condition studied
Coronary artery disease with angina pectoris

ICD-10 code
I25.11

ICD-10 code description
Atherosclerotic heart disease of native coronary artery with angina pectoris

Primary outcomes

1

Description
Troponin

Timepoint
Troponin measurement is done 12 to 24 hours before the angioplasty procedure and also 24 hours after the procedure.

Method of measurement
The level of troponin will be measured 12 to 24 hours before the procedure, exactly before receiving the first dose of the drug or placebo, and also 24 hours after the procedure by the laboratory technician with the HUBI TNI troponin quantitative kit.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, patients

will first receive 1 mg of colchicine (produced by Hashtgerd-Iran Mofid Pharmaceutical Company) 12 to 24 hours before the study and half a mg one hour later. Also, half an hour after the procedure, patients in the intervention group will receive a third dose of medicine equivalent to half a milligram of colchicine to maintain the anti-inflammatory effect of colchicine until 24 hours after the procedure.

Category

Treatment - Drugs

2

Description

Control group: Patients in the placebo control group, which is exactly the same as colchicine in terms of color and size, will receive the first dose 12 to 24 hours before and the second dose one hour later. They will also receive the third dose half an hour after the procedure. Also, the level of troponin before and 24 hours after the procedure in this group will be measured in the same way as the intervention group with a troponin quantitative kit by the laboratory technician.It should be noted that the content of placebo is starch, which is without complications for patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madani Heart Hospital

Full name of responsible person
Seyede Zohre Taheri

Street address
second floor, technical office, Lorestan University of Medical Sciences, Anoushirvan Rezaei Square

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Khorramabad

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Postal code
6813833946

Phone
+98 66 3322 9222

Email
dr.taheri96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Dr. Bahram Rasoolian

Street address
Khorramabad city, Anoushirvan Rezaei Square, Lorestan University of Medical Sciences

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Khorramabad

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Phone
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Email
bahramrasoulian@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Seyede Zohre Taheri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

Street address
Lorestan University of Medical Sciences, Anoushirvan Rezaei Square

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Person responsible for scientific inquiries

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Name of organization / entity

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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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Demographic information of patients without revealing their names, data from statistical analysis, information related to the main outcome of the study

When the data will become available and for how long
Up to one year after completing the study

To whom data/document is available
All members of society

Under which criteria data/document could be used
After statistical analysis

From where data/document is obtainable
Principal investigator

What processes are involved for a request to access data/document
Application through the Honorable Deputy of University Research and Deputy of Research of Shahid Madani Hospital

Comments