Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Anti-inflammatory effect of cholchicine in acute coronary syndrome

Protocol summary

Study aim
Evaluation of anti-inflammatory effects of colchicine in patients with acute coronary syndrome

Design
This study will be performed as a phase 2 randomized double-blind randomized clinical trial on 80 patients with ST Elevated MI who are candidates for Primary PCI and present within less than 12 hours of the onset of pain.

Settings and conduct
Patients with ST Elevated MI who are candidates for Primary PCI and have referred to Rasoul Akram Hospital less than 12 hours after the onset of pain arerandomly (block randomization) and double-blind admitted to the study. One group will be treated with colchicine and one group will receive placebo In all patients, 2 cc of venous blood will be taken 24 hours after receiving the first dose of colchicine or placebo to measure IL 1B levels.

Participants/Inclusion and exclusion criteria
Inclusion criteria: A patient with ST Elevated MI who is a candidate for Primary PCI and presented within less than 12 hours from the onset of pain Conditions for not entering the study: 1. Cardiogenic shock or hemodynamic instability 2. Allergy to colchicine is known 3. Patients with a history of chronic kidney and liver disease 4. Thrombocytopenia or leukopenia 5. Pregnant or lactating women 6. Patients receiving CYP3A4 inhibitors 7. Patients who are already taking colchicine 8. Patients who have evidence of active or inflammatory infection 9. Patients with a history of previous AF and MI 11. Patients with a history of CABG 12. MI patients in the field of stent thrombosis

Intervention groups
The intervention group will receive colchicine 1 mg initially and 1 mg one hour after Primary PCI. . The control group will receive colchicine at the beginning and one hour after Primary PCI.

Main outcome variables
Assessment of interleukin 1B levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210423051047N2**
Registration date: **2021-09-10, 1400/06/19**
Registration timing: **retrospective**

Last update: **2021-09-10, 1400/06/19**
Update count: **0**

Registration date
2021-09-10, 1400/06/19

Registrant information

Name
somayyeh nasiripour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 86701

Email address
nasiripours@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-27, 1400/04/06

Expected recruitment end date
2021-07-27, 1400/05/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Anti-inflammatory effect of cholchicine in acute coronary

syndrome

Public title
Colchicine in patients with myocardial infarction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A patient over 20 years of age with ST Elevated MI who is a candidate for Primary PCI and presented within less than 12 hours of the onset of pain
Exclusion criteria:
Cardiogenic shock or hemodynamic instability Known hypersensitivity to colchicine Patients with a history of chronic kidney and liver disease Thrombocytopenia or leukopenia Pregnant or lactating women Patients receiving CYP3A4 inhibitors Patients already taking colchicine Patients who have evidence of active or inflammatory infection Patients with a history of AF or MI Patients with a history of CABG MI patients in the field of stent thrombosis
Age
From **20 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
80 patients, using random allocation software, were randomly divided into two groups. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers. The tool used is random allocation software version 2.0 in which by selecting the number of groups and the sample size, a random sequence sheet is provided for the control and intervention group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be Triple-blind. The treating physician and patients will be blinded to the type of intervention and the data analyzer who must analyze the data]will be blinded to the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
14496-14535
Approval date
2021-02-22, 1399/12/04
Ethics committee reference number
IR.IUMS.REC.1399.1296

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction
ICD-10 code
I21
ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Assessment of interleukin 1B levels
Timepoint
24 hours after intervention
Method of measurement
Elisa Kit

Secondary outcomes

1

Description
Evaluation of recurrent myocardial infarction
Timepoint
On a daily basis from the start of the intervention
Method of measurement
Follow-up of symptoms of myocardial infarction

Intervention groups

1

Description
Intervention group: Patients receive 1 mg colchicine tablet made by Modava Pharmaceutical Company as 1 mg at first and 1 mg one hour after Primary PCI
Category
Treatment - Drugs

2

Description
Control group: Patients receive colchicine placebo made in the laboratory of Islamic Azad School of Pharmacy at the beginning and one hour after Primary PCI.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Somayyeh Nasiripour
Street address
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Sponsors / Funding sources

1

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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
Iran University of Medical Sciences
Proportion provided by this source
1
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
Iran University of Medical Sciences
Full name of responsible person
Maryam Farasatinasab
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Assistant Professor of Clinical Pharmacy
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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
The study report will be available as an article
When the data will become available and for how long
September 2021
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Upon written request and the protection of the rights of the study authorities, the approved items above will be available.
From where data/document is obtainable
Dr. Somayyeh Nasiripour, Assistant Professor of Clinical Pharmacy, Iran University of Medical Sciences Email: Nasiripours@yahoo.com
What processes are involved for a request to access data/document
Upon a written request, the study authorities will review it and then provide the documentation at its discretion.
Comments