Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Anti-inflammatory Effects of Colchicine on Thrombolysis in myocardial infarction (TIMI) flow grade, Myocardial Perfusion Grade (MPG) and no-reflow rate in patients undergoing Primary Percutaneous coronary intervention (PCI) in acute MI phase

Protocol summary

Study aim

Anti-inflammatory Effects of Colchicine on Thrombolysis in myocardial infarction (TIMI) flow grade, Myocardial Perfusion Grade (MPG) and no-reflow rate in patients undergoing Primary Percutaneous coronary intervention (PCI) in acute MI phase

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment that 320 patients diagnosed with Acute STEMI to perform Primary PCI are introduced to the Department of Cardiology, in the Heart Center of Tehran, who have criteria for entry will be included in the study. Patients, are divided to the two groups of 160 A and B, based on Permuted Block Randomization randomly.

Settings and conduct

This is a selective interventional study in which 320 patients diagnosed with Acute STEMI to perform Primary PCI are introduced to the Department of Cardiology, Tehran University of Medical Sciences, which, if they have criteria for entering the study, are selected and entered Will be studied

Participants/Inclusion and exclusion criteria

Entry requirements (Inclusion Criteria): patient older than 18 years of age who becomes a Primary PCI candidate؛ chest pain for less than or equal to 12 hours؛ Obtain consent from the patient؛ Exclusion Criteria: Patients who are only undergoing angiography for diagnosis؛ Patients who are being treated with Cholchicine due to chronic illness؛

Intervention groups

Patients are categorized randomly according to defined criteria in two groups of 160 patients. In one group, 1 mg of Colchicine tablet 1 hour before angioplasty and 0.5 mg of tablet، 1 hour after PCI, in addition to other routine treatments It will be given. In the other group, placebo is given. Then, anti-inflammatory effects of Colchicine on coronary flow and myocardial perfusion in the two groups will be investigated.

Main outcome variables

Coronary Flow Rate؛ Myocardial perfusion rate؛

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120111008698N23**
Registration date: **2018-07-15, 1397/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-15, 1397/04/24**
Update count: **0**

Registration date

2018-07-15, 1397/04/24

Registrant information

Name

Azita Hajhossein Talasaz

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-02-26, 1396/12/07
Expected recruitment end date
2018-09-21, 1397/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Anti-inflammatory Effects of Colchicine on Thrombolysis in myocardial infarction (TIMI) flow grade, Myocardial Perfusion Grade (MPG) and no-reflow rate in patients undergoing Primary Percutaneous coronary intervention (PCI) in acute MI phase

Public title
Evaluation of anti-inflammatory effects of colchicine on the blood flow of heart's vessels and heart's muscle in patients who undergo angioplasty in the acute phase of heart attack
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for the Primary PCI Pain or chest discomfort greater than or equal to 20 minutes, less than or equal to 12 hours, and ST elevation ≥ 1 mm in the adjacent limb leads and precordial leads except for V2, V3, or ST elevation ≥ 2 mm in V2, V3 in men or ST height ≥ 1.5 mm in V2, V3 in women. Obtain informed consent from all patients before enrollment
Exclusion criteria:
Patients who are only undergoing angiography for diagnostic purposes and do not undergo PCI Patients who have been treated with Colchicine due to chronic illness Colchicine intolerance history Glumerolar filtration Rate less than 30 ml/min and Dialysis patients Malignancy and infection Oral steroids or NSAIDs (Except for aspirin) within 72 hours prior to PCI Use of CYP 3A4 / P-glycoprotein inhibitor drugs (Ritonavir / Ketoconazole / Clarithromycin / Cyclosporine / Diltiazem / Vrapaemia) Patients who suffered cardiac arrest, cardiogenic shock (systolic pressure less than 90), VF, or under CPR in emergency setting Start angina more than 12 hours
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **320**

Randomization (investigator's opinion)
Randomized
Randomization description
In this study, Permuted Block randomization method was used individually. The randomized list of numbers 1 to 320 is randomly divided into two groups A or B, and the admitted patients are listed in group A or B, respectively.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, both participants and researchers, all physicians involved in the treatment of patients are unaware of the allocation of study groups, and those who prepare a draft article are also kept blind to the allocation of blind study groups Patients in group A or B and receiving a drug or placebo by the patient are unaware.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-02-25, 1396/12/06
Ethics committee reference number
61 IR.TUMS.VCR.REC.1396.4629

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
coronary blood flow and myocardial perfusion
Timepoint
during angiography
Method of measurement
TIMI flow criteria and observations during the angiography

Secondary outcomes

1

Description
hs-CRP
Timepoint
baseline and 48 hours after PCI
Method of measurement
blood sample

2

Description
TNT
Timepoint
baseline and 6 hours and 24 hours and 48 hours after PCI
Method of measurement
blood sample

3

Description
P-selectin
Timepoint
baseline and 24 hours after PCI
Method of measurement
blood sample

4

Description
30 day MACE
Timepoint
one month after PCI
Method of measurement
follow-up visit or phone call

Intervention groups

1

Description
Intervention group: Oral colchicine (Modava, Tehran) 1mg followed by 0.5 mg after PCI
Category
Treatment - Drugs

2

Description
Control group: Placebo of colchicine was administered at the dose of 1 mg followed by 0.5 mg after one hour of PCI
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Hajhossein Talasaz Azita
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Tehran Herat Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology of Tehran University of Medical Sciences
Full name of responsible person
Dr Masud Yunesian
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Department of Environmental Health Engineering, School of Public Health, Tehran University of Medical Sciences
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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
Deputy of Research and Technology of Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr.Seyed Hossein Hosseini

Position
Pharmacotherapy Resident

Latest degree
Master

Other areas of specialty/work
Medical Pharmacy

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Web page address

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
Data such as primary and secondary outcome information

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

Conditions for using the data or documentation will be determined depending on the type of use, with the coordinator of the project

From where data/document is obtainable

E-mail: a-talasaz@tums.ac.ir

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

E-mail: a-talasaz@tums.ac.ir

Comments