

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 Colchicine 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

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

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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 Glomerular 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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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,
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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
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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

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