Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effects of Colchicine on corrected Thrombolysis In Myocardial Infarction (TIMI) frame in ST segment elevation myocardial infarction patients undergoing primary percutaneous coronary intervention (PPCI)

Protocol summary

Study aim
assessment of Colchicine effect in improvement of PPCI in patients with STEMI

Design
double blind randomized clinical trial which will be done in 60 patients with STEMI between May 2017 and May 2018.

Settings and conduct
The investigation will be performed in Imam Reza and Qaem Hospitals in Mashhad and Colchicine and placebo will be coded by pocket and researcher and patient will be blinded to its content.

Participants/Inclusion and exclusion criteria
Inclusion criteria: stability for at least previous 6 months, ability for participation in followups, consent for enter in the study, Anterior ST elevation MI Exclusion criteria: contraindication of Colchicine consumption, Infectious disorder or active inflammatory disorder or known malignancy, current treatment by Corticosteroid or other anti-inflammatory drugs, known sensitivity to Colchicine or current treatment by Colchicine, severe renal failure (GFR<30), liver failure, cardiac arrest, ventricular fibrillation or symptomatic cardiogenic shock, stent thrombosis, occurrence of angina 48 hours before infarction, previous myocardial infarction, left main coronary artery or left circumflex occlusion, existence of metal implant, pregnancy

Intervention groups
Patients with anterior STEMI in last 12 hours presented by chest pain and referred to Qaem and Imam Reza Hospitals and first will undergo angiography then PCI will entered in the study and randomly will be assigned in intervention (treatment by Colchicine) and control (treatment by placebo) groups.

Main outcome variables
PPCI result improvement by corrected TIMI frame count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180127038515N1**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**

Registration date
2018-03-19, 1396/12/28

Registrant information

Name
Samaneh Hassanzadeh Avval

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3854 3031

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-21, 1396/02/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of effects of Colchicine on corrected Thrombolysis In Myocardial Infarction (TIMI) frame in ST segment elevation myocardial infarction patients undergoing primary percutaneous coronary intervention (PPCI)

Public title
Effect of Colchicine in improvement of myocardial infarction patients undergoing therapeutic intervention
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
stability for at least previous 6 months ability for participation in followups consent for enter in the study
Exclusion criteria:
contraindication of Colchicine consumption infectious disorder or active inflammatory disorder or known malignancy current treatment by Corticosteroid or other anti-inflammatory drugs known sensitivity to Colchicine or current treatment by Colchicine severe renal failure (GFR<30) liver failure cardiac arrest ventricular fibrillation or symptomatic cardiogenic shock stent thrombosis occurrence of angina 48 hours before infarction previous myocardial infarction left main coronary artery or left circumflex occlusion existence of metal implant pregnancy
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
participants and researcher will be blinded by coded-pockets toward administrating drugs.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138735499
Approval date
2017-01-04, 1395/10/15
Ethics committee reference number
IR.MUMS.fm.REC.1395.487

Health conditions studied

1

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

Primary outcomes

1

Description
corrected TIMI frame count index
Timepoint
before starting PCI, after doing PCI
Method of measurement
By using angiography device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: administration of 2mg Colchicine
Category
Treatment - Drugs

2

Description
Control group: administration of 2mg placebo tablet
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Ali Eshraghi

Street address
Imam Reza Square

City
Mashhad

Province
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9137913316

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+98 51 3854 3031

Email
eshraghia@mums.ac.ir

Web page address
http://emamreza.mums.ac.ir/index.php

2

Recruitment center

Name of recruitment center
Qaem Hospital

Full name of responsible person
Ramin Khamene Bagheri

Street address
Shariati Square

City
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http://quaem.mums.ac.ir/index.php

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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ramresearch@mums.ac.ir

Web page address
http://v-research.mums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Samaneh Hassanzadeh Avval

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

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Person responsible for scientific inquiries

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Position
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Specialist
Other areas of specialty/work
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Article in journals and report in conferences and seminar
When the data will become available and for how long
unlimited
To whom data/document is available
general academic or non-academic researcher
Under which criteria data/document could be used
By getting permission from main researcher of this project
From where data/document is obtainable
main researcher of project
What processes are involved for a request to access data/document
sending request to main researcher of the project and after validation the data will be send to requester
Comments