

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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)

Phone

+98 51 3854 3031

Email address

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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 administering 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

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

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Razavi Khorasan

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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

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ramin Khameneh Bagheri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Cardiovascular department, First floor, Qaem
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Person responsible for updating data

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

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