Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Colchicine on Infarct Size in Patients With Ant STEMI who Receiving Thrombolytic Therapy:Randomized Controlled Preliminary Study.

Protocol summary

Summary

The study population comprises patients with a first anterior myocardial infarction candidate for thrombolytic treatment, referred to emergency room of Shahid Madani Hospital,Tabriz. In this double-blind study patients are randomized to two placebo and colchicines groups. Systematic randomization will be performed using computer-generated numbers by a nurse who was not involved in the treatment. The intervention group receives 2 mg of colchicines before thrombolytic treatment. Then colchicines will be given at 0.5 mg twice daily for 5 days. The patients in control group will receive the same dose of placebo. The subjects with the following condition will be excluded from our study:80 years old, history of allergy to colchicines or taking colchicines, receiving NSIADS, corticosteroids, patients diagnosed with inflammatory active diseases or cancer, renal failure, liver failure as well as the ones with carcinogenic shock, cardiac arrest or ventricular fibrillation, history of myocardial revascularization, thrombocytopenia and leucopenia. It should be noted that the initial and subsequent doses will depend on kidney and liver function test results (Bill, total, albumin, INR). Thus the subjects with kidney and liver failure will be excluded, too. Cardiac enzymes will be measured every 4-6 hours for 48 hours. Then the peak cardiac enzymes and their average will be measured. The left ventricular function will be quantified based on the echocardiography reports in the patients' medical records performed by echocardiography physician. The cardiovascular events during hospitalization will be monitored and included in the study. Our checklist will include information on the basic variables, such as age, gender, infarction location, and coronary risk factors. Finally the participants in two groups will be compared in terms of enzyme infarct size, left ventricular systolic function and cardiovascular events during hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090523905N1**
Registration date: **2015-12-21, 1394/09/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-21, 1394/09/30

Registrant information

Name
Jafar Arda
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Cardiovascular Research Center, Tabriz University Of Medical Sciences, Tabriz, Iiran

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Colchicine on Infarct Size in Patients With Ant STEMI who Receiving Thrombolytic Therapy:Randomized Controlled Preliminary Study.

Public title
Effect of Colchicine on Infarct Size With Myocardial Infarction
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: Both male and female;>20 years old; patients with a first anterior myocardial infarction candidate for thrombolytic treatment; exclusion criteria: >80 years old; known hypersensitivity-allergy to colchicine;under chronic treatment with colchicine;receiving NSIADS; active inflammatory diseases or known malignancy; severe renal failure;hepatic failure;presenting with cardiogenic shock;presenting with cardiac arrest or ventricular fibrillation; history of myocardial revascularization; thrombocytopenia; leucopenia
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences,Tabriz,Iran
City
Tabriz
Postal code
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
TBZMED.REC.1394.75

Health conditions studied

1

Description of health condition studied
Myocardial Infarction
ICD-10 code
I20-I25
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
Infarct size of Myocardial Infarction
Timepoint
48 Hour After Intervention
Method of measurement
Check Myocardial Enzymes

Secondary outcomes

1

Description
Myocardial Function
Timepoint
Hospitalization
Method of measurement
Echocardiography

Intervention groups

1

Description
In colchicine group, at the beginning 2 mg of Colchicine will be administered as loading dose, then 0.5 mg of Colchicine twice daily for five days as maintenance dose.
Category
Treatment - Drugs

2

Description
In Placebo group, at the beginning 2 mg of Placebo will be administered as loading dose, then 0.5 mg of Placebo twice daily for five days as maintenance dose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
SHahid Madani Cardiovascular Hospital
Full name of responsible person
Jafar Arda
Street address
SHahid Madani Hospital, Tabriz, East Azerbaijan
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ahmad Separham
Street address
SHahid Madani Cardiovascular Hospital,Tabriz
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty