

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 NSAIDs, 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

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 3958

Email address

ardaj@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Cardiovascular Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

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

City

Tabriz

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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ahmad Separham

Position

Assistant Professor

Other areas of specialty/work

Street address

SHahid Madani Hospital, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3337 3958

Fax

Email

aseparham@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Naser Aslanabadi

Position

Professor

Other areas of specialty/work

Street address

SHahid Madani Hospital, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3337 3958

Fax

Email

aslanabadin@gmail.com aslanabadin.tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Jafar Arda

Position

Assistant

Other areas of specialty/work

Street address

SHahid Madani Hospital

City

Tabriz

Postal code

Phone

+98 41 3337 3958

Fax

Email

ardaj@tbzmed.ac.ir jafar.arda.ja@gmail.com

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