Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of low dose cholchicine on LV function after myocardial infarction based on usual and strain echocardiography

Protocol summary

Study aim
Invastigating the effect of low dose colchicine after myocardial infarction on left ventricular function based on normal and strain echocardiography findings.

Design
A controlled, double-blind, randomized, phase 3 clinical trial on 96 patients. The rand function of Excel software was used for randomization

Settings and conduct
This double-blind study will be conducted in Tabriz Shahid Madani Hospital and 96 patients with acute anterior myocardial infarction will be divided into 2 intervention and control groups by generating random numbers using Excel software, and 48 patients will be in each group.Patients and medical personnel do not know the type of pills in the box, and only the researcher knows the type based on the code written on the pill box. The shape, color, and size of the drug and placebo are the same, so blinding at the participant level is also done well.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the study include patients with anterior STEMI. The main exclusion criteria include: known sensitivity to colchicine or current chronic treatment with colchicine, severe renal failure and severe liver failure.

Intervention groups
The intervention group includes patients with acute anterior myocardial infarction who receive colchicine. The comparison group includes patients with acute anterior myocardial infarction who receive placebo

Main outcome variables
Left ventricular function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231223060504N1**
Registration date: **2024-01-16, 1402/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-16, 1402/10/26**
Update count: **0**

Registration date
2024-01-16, 1402/10/26

Registrant information

Name
Niloofar Salari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-31, 1402/10/10

Expected recruitment end date
2024-05-30, 1403/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of low dose cholchicine on LV function after myocardial infarction based on usual and strain echocardiography

Public title

Investigating the effect of colchicine on left ventricular function based on conventional and strain echocardiography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with acute anterior STEMI will be included in the study.

Exclusion criteria:

stroke in the last 3 months Type 2 Index MI CABG in the last 3 years or decision to undergo surgery History of non-skin malignancies in the last 3 years Inflammatory bowel disease (IBD) Chronic diarrhea Neuromuscular diseases with a CK level greater than 3 times the maximum normal (except for diseases that have led to muscle infarction) Chronic hematological diseases Current treatment with corticosteroids or other anti-inflammatory drugs Known sensitivity to colchicine or current chronic treatment with Colchicine Severe kidney failure (Cr>2 upper limit of the normal range) Severe liver failure History of alcohol or drug abuse

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

96 patients are divided into intervention and control groups by using the creation of random numbers by Excel software (48 patients in each group), randomization is done in a simple way and is done in the individual randomization unit. The randomization tool is a table of numbers. Random numbers are generated in 2 groups A and B, the numbers of group A are used for the intervention group and the numbers of group B are used for the control group according to the randomly created sequence, and finally each patient (according to the time of hospitalization) may be in each of be placed in 2 groups.According to the randomly created number, medical personnel and patients are not aware of the type of pills they receive, only the researcher is aware of it based on the code inserted on the pill box, so this study is a double-blind clinical trial. 48 patients in each treatment arm are randomly assigned to receive placebo or colchicine.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were told that they could receive colchicine or placebo. Therefore, patients are not aware of their treatment group. Patients and medical personnel do not know the type of pills that are in the boxes (colchicine or placebo). Only the researcher is aware of it based on the code inserted on the pill box, so this study is a double-blind parallel clinical trial study.The drug and placebo are completely similar in terms of shape, size and color, so blinding at the participant level will be done well

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5165747635

Approval date

2023-11-25, 1402/09/04

Ethics committee reference number

IR.TBZMED.REC.1402.625

Health conditions studied

1

Description of health condition studied

Acute anterior STEMI

ICD-10 code

I21.0

ICD-10 code description

ST elevation (STEMI) myocardial infarction of anterior wall

Primary outcomes

1

Description

Left ventricle function

Timepoint

The effect of colchicine on left ventricular function at the beginning of the study (before the start of the intervention) and 4 to 6 weeks after administration

Method of measurement

Echocardiography machine

Secondary outcomes

empty

Intervention groups

1

Description
A total of 966 tablets (the total number of tablets required for distribution among the intervention group) of Colchicine 1 mg manufactured by Sinapishgam Daru Novin Company will be prepared. Each patient will be given 21 tablets to use half a tablet daily for 42 days (6 weeks).
Category
Treatment - Drugs

2

Description
966 placebo pills (the total number of pills needed to be distributed among the control group) are made for use in 48 patients of the control group in the pharmaceutical laboratory of Tabriz Faculty of Pharmacy, and starch and magnesium stearate are used as lubricants. In terms of shape, color and size, it is exactly the same as colchicine tablets of Sinapishgam Daro Navin company. Each control group patient is given 21 tablets (placebo) to use half a tablet daily for 42 days (6 weeks).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Shahid Madani hospital
Full name of responsible person
Niloofar Salari
Street address
No. 7, Golgasht, Shahid Madani Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
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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
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
Tabriz University of Medical Sciences
Full name of responsible person
Niloofar Salari
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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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
Part of the data, such as information about the main outcome

When the data will become available and for how long
6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The use of the data of this study will be allowed for researchers and scientific personalities.

From where data/document is obtainable
Dr. Niloofar Salari salari.niloofar@ymail.com 09132489115 Tabriz Shahid Madani Hospital Research Center

What processes are involved for a request to access data/document
Applicants will be able to receive the data of this study by visiting or contacting the research center of Tabriz Shahid Madani Hospital.

Comments