Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Colchicine in prevention of Pericardial Effusion after CABG, randomized clinical trial

Protocol summary

Study aim
Determining the effect of colchicine on the prevention of pericardial effusion after CABG

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 400 patients, randomized by Block Random Allocation and using rendomizer software

Settings and conduct
The studied patients will be randomly divided into two groups of patients receiving colchicine and the control group.Patients in the first group will be given 0.5 mg of colchicine every 12 hours for 48 hours before surgery and 0.5 mg daily orally until discharge if they weigh less than 70 kg. Patients in the second group will be given a placebo similar to the conditions in the first group. Therapists and evaluators will not be informed of the assignment of individuals to study groups, and the type of medication prescribed. The task of assigning individuals to study groups will be with the research fellow epidemiologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria _All patients referred to Fatemeh Zahra Sari Heart Hospital with coronary artery disease who are candidates for coronary artery bypass surgery exclusion criteria _ age over 80 years, presence of pericardial effusion in preoperative trans-thoracic echo, presence of pleural effusion in preoperative CXR, chronic liver or lung or kidney disease, other concomitant heart surgeries, patients already Were receiving colchicine or were allergic to colchicine

Intervention groups
Patients in the intervention group will be given 0.5 mg of colchicine every 12 hours for 48 hours before surgery (0.5 mg daily if they weigh less than 70 kg) orally until discharge. Patients in the control group will also be given a placebo similar to the conditions in the first group.

Main outcome variables
pericardial effusion

General information

Reason for update
Due to the recalculation of the sample size and the appropriate power of the study with a smaller number of cases, the sample size was modified with the coordination of the statistics colleague and the approval of the Research Center of the Heart Center of Mazandaran University of Medical Sciences.

Acronym

IRCT registration information
IRCT registration number: **IRCT20211221053477N1**
Registration date: **2022-09-14, 1401/06/23**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-11, 1402/10/21**
Update count: **1**

Registration date
2022-09-14, 1401/06/23

Registrant information

Name
Mohammad hosein Taghvayi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 4252 4557

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taghvayim1372@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2023-05-24, 1402/03/03

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Colchicine in prevention of Pericardial Effusion after CABG, randomized clinical trial

Public title
The Effect of Colchicine in prevention of Pericardial Effusion after CABG
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All patients referred to Fatemeh Zahra Heart Hospital with coronary artery disease who are candidates for coronary artery bypass graft surgery
Exclusion criteria:
Patients over 80 years old Presence of pericardial effusion in preoperative trans-thoracic echo Existence of pleural effusion in CXR standing before surgery Chronic lung, liver disease (known case of liver disease or LFT more than 3 times normal) and kidney disease (known case of kidney disease or Cr> 2.5) Other heart surgeries at the same time as coronary artery bypass grafting Patients who was allergic reaction to colchicine or given colchicine in any way are contraindicated pregnant patients Patients receiving colchicine before starting of study
Age
To **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **260**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomly, by block method (Block Random Allocation) with variable block sizes (multiples of 2) and using randomizer software, they will be divided into two groups of patients receiving colchicine and the control group. Based on this setting, the drugs prepared They are coded (with two letters and three numbers) and numbered in sequence. During the study, in the order of entry of eligible people into the study, the considered medicine (by number) will be provided to the patients. After that, all the patient's information will be recorded in the information collection forms based on the code inserted on the medicine (as the patient's identifier).
Blinding (investigator's opinion)
Double blinded
Blinding description
Therapists and evaluators will not be informed of the assignment of individuals to study groups, and the type of medication prescribed. The task of assigning individuals to study groups will be with the research fellow epidemiologist. During the study, in order for the eligible people to enter the study, the intended medicine (according to the number) will be provided to the patients. From then on, all patient information will be recorded in data collection forms based on the code entered on the drug (as a patient identifier).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of mazandaran university of medical sciences
Street address
artesh street
City
sari
Province
Mazandaran
Postal code
13371418188
Approval date
2022-01-09, 1400/10/19
Ethics committee reference number
ir.mazums.rec.1400.639

Health conditions studied

1

Description of health condition studied
post cabg pericardial effusion
ICD-10 code
ICD-10 code description

2

Description of health condition studied
post cabg pericarditis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pericardial effusion
Timepoint
Before discharg and 14 days after surgery
Method of measurement
echocardiography

Secondary outcomes

1

Description
Pleural effusion
Timepoint
Before discharge and 14 days after surgery
Method of measurement
echocardography

2

Description
Pericarditis
Timepoint
Before discharge and 14 days after surgery
Method of measurement
Echocardiography and clinical history

Intervention groups

1

Description
Intervention group: Patients in the intervention group will be given 0.5 mg of colchicine every 12 hours for 48 hours before surgery and 0.5 mg daily orally until discharge if they weigh less than 70 kg. befor discharge and two weeks after that, patients undergo transthoracic echocardiography again and the presence or absence of pericardial and pleural effusions is recorded. The drug used in the form of 1 and 0.5 mg tablets produced by the mofid company and under the brand name of Madasin.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group will be given a placebo similar to the conditions in the intervention group. During discharge and two weeks later, patients will undergo transthoracic echocardiography again and the presence or absence of pericardial and pleural effusions will be recorded.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital
Full name of responsible person
Rozita Jalalian
Street address
Artesh street
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Sari
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Mazandaran
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1337148188
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crc@MAZUMS.AC.IR
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohamad Hosein Taghvayi
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1337148188
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Email
crc@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Mohamad Hosein Taghvayi

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

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Person responsible for scientific inquiries

Contact

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Mazandaran University of Medical Sciences

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Mohammad hosein Taghvayi

Position
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Latest degree
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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
Yes - There is a plan to make this available

Title and more details about the data/document
Apart from the name and contact number, other information about the participants can be published

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

To whom data/document is available
This data will be available to researchers working in scientific institutes

Under which criteria data/document could be used
This documentation can be used by researchers and physicians

From where data/document is obtainable
researchers can access this information by visiting or contacting the research center of Fatemeh Al-Zahra Hospital in Sari

What processes are involved for a request to access data/document
After establishing a connection between the research center of Fatemeh Al-Zahra Hospital in Sari and if the eligibility of the applicant is confirmed, the information will be provided to the person within one month.

Comments