

# 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 randomizer 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)

##### Phone

+98 11 4252 4557

##### Email address

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 discharge 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**

echocardiography

## 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. before 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

#### **City**

Sari

#### **Province**

Mazandaran

#### **Postal code**

1337148188

#### **Phone**

+98 11 3331 4086

#### **Email**

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

#### **Street address**

Artesh street

#### **City**

sari

#### **Province**

Mazandaran

#### **Postal code**

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#### **Phone**

+98 11 3331 4086

#### **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

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad hosein Taghvayi

**Position**

Rsident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad hosein Taghvayi

**Position**

Rsident

**Latest degree**

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**Other areas of specialty/work**

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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**