

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Effect of Colchicine on the prevention of Atrial Fibrillation after Coronary Artery Bypass Grafting surgery(CABG); a Clinical Trial Study

#### Protocol summary

##### Study aim

Determining the Effect of Colchicine on the Prevention of Atrial Fibrillation after Coronary Artery Bypass Grafting(CABG)

##### Design

Clinical trial with control group, with parallel groups, double-blind, phase 2 on 230 patients

##### Settings and conduct

Fatemeh Zahra Sari Heart Center, affiliated to Mazandaran University of Medical Sciences, in this study, a data collection form designed by the research team will be used to collect information. In the first part, demographic Characteristics of Patients and in the second part, related information. The patient will be recorded for Hospitalization and Treatment such as Atrial Fibrillation, number of Days hospitalized in the ICU, number of Days hospitalized and the incidence of complications due to Colchicine consumption such as gastrointestinal intolerance, etc. Patients and outcome analysts are blinded.

##### Participants/Inclusion and exclusion criteria

Entry conditions: All of the Patients with Coronary Artery Disease that are Candidates for Coronary Artery Bypass Grafting surgery

##### Intervention groups

In this Study, 230 Patients with Entry Conditions 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 if they weigh less than 70 kg, until discharge. Patients in the second group will also be given a placebo, similar to the conditions in the first group.

##### Main outcome variables

Duration of ICU hospitalization, Duration of hospitalization, Atrial fibrillation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220515054855N1**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

##### Registration date

2022-09-05, 1401/06/14

##### Registrant information

##### Name

Babak Bagheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3332 3023

##### Email address

babakbagheri975@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-20, 1401/02/30

##### Expected recruitment end date

2022-11-20, 1401/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Colchicine on the prevention of Atrial Fibrillation after Coronary Artery Bypass Grafting surgery(CABG); a Clinical Trial Study

#### Public title

Effect of Colchicine on the Prevention of Atrial Fibrillation after Coronary Artery Bypass Grafting Surgery(CABG)

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All patients with coronary artery disease who are candidates for coronary artery bypass graft surgery.

##### Exclusion criteria:

#### Age

To **80 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **230**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random block method using randomizer software

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

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 if they weigh less than 70 kg until discharge. 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. Setting for assigning Individuals to Study Groups will be with the Project Epidemiologist.

#### 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

Municipality Square., Army Blvd., Next To The Blood Transfusion Organization

#### City

Sari

#### Province

Mazandaran

#### Postal code

4818813371

#### Approval date

2022-04-24, 1401/02/04

#### Ethics committee reference number

IR.MAZUMS.REC.1401.049

### Health conditions studied

#### 1

##### Description of health condition studied

Atrial Fibrillation

##### ICD-10 code

I00-I99

##### ICD-10 code description

بیماری های قلب و عروق

### Primary outcomes

#### 1

##### Description

Atrial fibrillation

##### Timepoint

Monitoring until discharge

##### Method of measurement

monitiring in icu

### Secondary outcomes

#### 1

##### Description

Duration of hospitalization

##### Timepoint

From CABG surgery to hospital discharge

##### Method of measurement

monitoring

### Intervention groups

#### 1

##### Description

Intervention group: Patients in the intervention group will be given orally 0.5 mg of colchicine every 12 hours 48 hours before surgery, and 0.5 mg daily until discharge if they weigh less than 70 kg. The patients will be monitored during hospitalization and if any Atrial fibrillation or its absence and the duration of hospitalization are recorded in the patient's checklist.

##### Category

Treatment - Drugs

## 2

### Description

Control group: Patients in the control group will be given a placebo similar to the conditions of the intervention group. Patients are monitored during hospitalization, and if atrial fibrillation occurs or not, and the duration of hospitalization is recorded in the patient checklist.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatemeh Al-Zahra Teaching Hospital

##### Full name of responsible person

Babak Bagheri

##### Street address

Municipality Square., Army Boulevard., Sari Town

##### City

Sari

##### Province

Mazandaran

##### Postal code

4818813371

##### Phone

+98 11 3332 3023

##### Email

bbagheri@mazums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Younes panahi

##### Street address

Mazandaran University of Medical Science., 18th Kilometers of Farahabad road., Sari Town

##### City

Sari

##### Province

Mazandaran

##### Postal code

4847191971

##### Phone

+98 11 3304 4000

##### Email

bbagheri@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

50

##### 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

Babak Bagheri

##### Position

Associate Professor of Cardiology

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Cardiology

##### Street address

Fatemeh zahra Hospital., Municipality Squar., Artesh blvd., Sari Town

##### City

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##### Province

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##### Postal code

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##### Phone

+98 11 48 33323023

##### Email

bbagheri@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Babak Bagheri

##### Position

Associate professor

##### Latest degree

Subspecialist

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

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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**

All data can be shared

**When the data will become available and for how long**

after publishement

**To whom data/document is available**

every one

**Under which criteria data/document could be used**

without roules

**From where data/document is obtainable**

Publisher Magazine Website

**What processes are involved for a request to access data/document**

search

**Comments**