

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

Sari

Province

Mazandaran

Postal code

4818813371

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

Other areas of specialty/work

Cardiology

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City

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Province

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4818813371

Phone

0098 11 3323023

Email

bbagheri@mazums.ac.ir

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