Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 rendomizer 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 fibrilation
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
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Mazandaran
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4818813371
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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 Kiloometers of Farahabad road., Sari Town
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4847191971
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+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
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Subspecialist
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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
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