

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effects of low dose colchicin in prevention of atrial fibrillation after coronary artery bypass graft (A Placebo-Controlled Randomized Clinical Trial)

Protocol summary

Summary

Main objectives of the study are the effect of administration of low dose colchicine on the incidence of atrial fibrillation, ICU (Intensive Care Unit) stay and hospital stay following coronary bypass surgery in the intervention and control groups. It is told to the patients that they may take colchicine or placebo in the informed consent. Therefore, patients are not aware of their therapeutic group. The patients and medical personnel are not aware of the type of tablets in the boxes (colchicine or placebo). Only the researcher is aware of the code written on the boxes of the tablets; so, this study is a double-blind, parallel clinical trial. Inclusion criteria include patients with coronary artery disease (on angiography). Exclusion criteria are patients above 80 years old, patients with heart valve disease or arrhythmia, history of using anti-arrhythmic drugs or pacemaker. Two hundred-sixteen patients using random numbers (created by computer) are divided into intervention and control groups. Thus, 108 cases in each treatment arm are randomized to receive placebo or colchicine. In the intervention group, a total of 7.0 mg oral colchicine is administered as: 1.0 mg, the night before surgery and also 1.0 mg, on the morning of surgery and then from the first day after operation followed by a maintenance dose of 0.5 mg twice a day for five days after surgery. Patients in the control group receive placebo (ineffective pill with similar size to colchicine). In this study, the main outcome variable is the atrial fibrillation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208043799N5**
Registration date: **2013-01-27, 1391/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-27, 1391/11/08

Registrant information

Name

Nasim Shayan

Name of organization / entity

Cardiac Transplantation Research Center (CTRC)

Country

Iran (Islamic Republic of)

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ctrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of low dose colchicin in prevention of atrial fibrillation after coronary artery bypass graft (A Placebo-

Public title

colchicin and prevention of atrial fibrillation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with coronary artery disease (on angiography) who are candidate for coronary artery bypass. Exclusion criteria: 1- Patients above 80 years old. 2- Patients who have atrial fibrillation before surgery. 3- Patients with heart valve disease or arrhythmia or having every degree of heart block conduction. 4- Patients who use a pacemaker. 5- Patients who have chronic lung, liver or kidney disease. 6- Patients who have other heart surgeries simultaneously with bypass surgery. 7- Patients who are allergic to colchicine or in any way giving colchicine to them is contraindicated. 8- Having sick sinus syndrome.

AgeFrom **40 years** old to **80 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **216****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2012-10-10, 1391/07/19

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes**1****Description**

AF rhythm

Timepoint

Continuous monitoring for the first 72 hours after CABG surgery and then daily ECG

Method of measurement

ECG recording device

2**Description**

Length of stay in ICU

Timepoint

At the time of transferring to the ward

Method of measurement

Refer to the data sheet in ICU

3**Description**

Duration of hospital stay

Timepoint

At discharge time

Method of measurement

Refer to the Patient file

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group with systolic blood pressure above 80 mmHg and rate of more than 60/min, a total of 7.0 mg oral Colchicine is administered as: 1.0 mg, the night before surgery and also 1.0 mg, on the morning of surgery and then from the first day after operation followed by a maintenance dose of 0.5 mg, twice a day in patients ≥ 70 kg and halved dose for patients < 70 kg for five days after surgery. Colchicine is an anti-inflammatory medication used to prevent and ease gout attacks. Colchicine is available as oral tablets. Each

scored tablet contains 1 mg Colchicine. This product is manufactured by Modava pharmaceutical company.

Category

Prevention

2**Description**

Patients in the control group receive placebo pills which are specifically designed to have no real effect. They are made of an inert substance. These tablets in terms of size, shape, packaging and name are exactly similar to the colchicin tablets. Only the code written on the boxes are different from each other. Frequency and duration of using placebo pills in the control group are absolutely the same as colchicine pills in the intervention group. This product is manufactured by Modava pharmaceutical company.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Shariati Hosoitai

Full name of responsible person

Nasim Shayan (Masters in management)

Street address

Dr. Shariati Hospital, North Karegar Ave.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Akbar Fotouhi (Research Deputy of Tehran University of Medical Sciences)

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Full name of responsible person

Nasim Shayan

Position

Executive director of Cardiac Surgery and Transplantation Research Center/ Masters in management

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Full name of responsible person

Dr. Mahmoodreza Sarzaeem

Position

Assistant professor of heart surgery

Other areas of specialty/work**Street address**

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Cardiac Surgery and Transplantation Research Center
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Full name of responsible person

Nasim Shayan

Position

Executive director of Cardiac Surgery and
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty