

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Colchicine in preventing post pericardiotomy syndrome

Protocol summary

Study aim

Aim of this study is effect of Colchicine in preventing post pericardiotomy syndrome.

Design

This is a clinical trial . 120 patients who underwent open heart surgery in Amiralmomenin Medical Center in Arak city in 2013.

Settings and conduct

This is a clinical trial and double blind. Patients who underwent open heart surgery in Amiralmomenin Medical Center in Arak city in 2013.we divided patients in two groups randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years and more than; open heart surgery indication Exclusion criteria: Contraindications for Colchicine; allergy to Colchicine; pregnancy and breastfeeding

Intervention groups

The case group received 1 mg twice a day after the first day of surgery, then 1 milligram daily for 1 month in patients with weight more than 70 kilogram and 0.5 milligram in patients with Weigh less than 70 kilogram. Control group: The control group received 1 milligram placebo twice a day after the first day of surgery, then 1 milligram daily for 1 month in patients with weight more than 70 kilogram and 0.5 milligram in patients with Weigh less than 70 kilogram.

Main outcome variables

effect of Colchicine in preventing post pericardiotomy syndrome(Incidence Atrial fibrillation and pericardial effusion)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N70**

Registration date: **2018-03-02, 1396/12/11**

Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**

Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Colchicine in preventing post pericardiotomy syndrome

Public title

The effect of Colchicine in preventing post pericardiotomy syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18 years and more than open heart surgery indication

Exclusion criteria:

Contraindication for consumption Colchicine allergy to Colchicine pregnancy and breastfeeding

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and care provider and data analyzer are unaware of the intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Approval date

2013-05-22, 1392/03/01

Ethics committee reference number

92-148-11

Health conditions studied

1

Description of health condition studied

post pericardiotomy syndrome

ICD-10 code

I32

ICD-10 code description

Pericarditis in diseases classified elsewhere

Primary outcomes

1

Description

atrial fibrillation

Timepoint

After cardiac surgery, discharge time, one month and six months later

Method of measurement

clinical examination, taking the electrocardiogram and, if necessary, electrocardiography

2

Description

Pericardial effusion

Timepoint

After cardiac surgery, discharge time, one month and six months later

Method of measurement

chest xray and Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The case group received 1 milligram Colchicine twice a day after the first day of surgery, then 1 milligram daily for 1 month in patients with weight more than 70 kilogram and 0.5 milligram in patients with Weigh less than 70 kilogram.

Category

Treatment - Drugs

2

Description

Control group: The case group received 1 milligram placebo twice a day after the first day of surgery, then 1 milligram daily for 1 month in patients with weight more than 70 kilogram and 0.5 milligram in patients with Weigh less than 70 kilogram.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Navidreza Mashayekhi

Street address

Amiralmomenin hospital, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Vice chancellor for research

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza rostami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Navidreza Mashayekhi

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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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

Not applicable

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Navidreza Mashayekhi

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

They have to write letters to the professors and the university

Comments