Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of colchicine effect on the post-pericardiotomy syndrome alleviation:a randomized, double blinded, placebo controlled study

Protocol summary

Study aim
: Investigation of colchicine effect on incidence of the post-pericardiotomy syndrome

Design
A randomized, parallel group, double blinde, placebo controlled trial ,100 cardiac surgery candidates

Settings and conduct
This study was conducted at cardiology Clinic of Imam Hussein Hospital. Patients are candidate for cardiac surgery by specialist if they are qualified to enter into the study. After complete information about the study is provided to the patients, drug/placebo will be delivered to the patient if agreed. past medical history ,Laboratory tests included CBC, , AST, ALT, Alp, BUN, Cr,CPK ,echocardiography will done. the incidence of post-pericardiotomy syndrome at 2 week after surgery will evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria were: candidate age ≥18 years, Patient agrees to enter the study exclusion criteria were not eligible liver functional test>1.5 times the upper normal limit Abnormal creatinine2.5mg/dl known myopathy elevated CPK gastrointestinal disease hypersensitivity to colchicine,

Intervention groups
cases: 50 cases, were treated for 48 hours pre-operation, with 1 mg colchicine ; one-dose each 12 hours for first two days. After surgery, patients were treated with 0.5 mg colchicine each 12 hour for 2 weeks. control: 50 patients, were treated for 48 hours pre-operation, with each 12 hours for first two days. After surgery, patients were treated with placebo each 12 hour for two weeks. After two weeks the PPS syndrome occurence were evaluated

Main outcome variables
the incidence of the PPS (Fever lasting beyond the first post-operative week without evidence of systemic or focal infection,Pleuritic chest pain,Friction rub,Evidence of pleural effusion,Evidence of pericardial effusion) the combined rate of disease-related hospitalization, cardiac tamponade, constrictive pericarditis, and recurrent pericarditis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120703010178N21**
Registration date: **2020-11-14, 1399/08/24**
Registration timing: **retrospective**

Last update: **2020-11-14, 1399/08/24**
Update count: **0**

Registration date
2020-11-14, 1399/08/24

Registrant information

Name
Mohammad Sistanizad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of colchicine effect on the post-pericardiotomy syndrome alleviation:a randomized, double blinded, placebo controlled study

Public title

evaluation of colchicine for the Prevention of the Post-pericardiotomy Syndrome (COPPS):

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing cardiac surgery, had no contraindication to colchicine, were able to provide informed consent. candidate for cardiac surgery by cardiologist age ≥18 years patients have to be willing and able to give informed consent and to comply with the study and follow-up.

Exclusion criteria:

known myopathy or elevated baseline pre-operative creatine kinase Liver problems serum creatinine upper than 2.5mg/dl Gastrointestinal problems pregnancy or OCP usage hypersensitivity to colchicine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization was done by block randomization method using a randomization table made with statistical software with four blocks and individual randomization unit. To hide this table, there is only one copy of this table without specifying the study groups that are maintained by the study host in the center.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, due to the use of tablets of similar weight and appearance and similar drug canisters, drugs and placebo can not be distinguished from each other. Medications are given with three-character codes, including two letters and one number. A cardiologist who introduces the patient to the study does not know what drug will be deliver to the patient. Due to the fact that it is not included in the randomization list of the study groups, the drug deliverer is blind to the delivered drug and, given the very similar appearance of the drug and the placebo, there is no way to determine the type of drug delivery for the patient and the investigator. The assessor is a self-delivering scholar who does not know the patient group. Only one person outside the study has a list of groups for each group, which only provides the original researcher if there is a report of serious side effect or the completion of study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, Shahid Chamran High Way

City

tehran

Province

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Postal code

1991953381

Approval date

2020-01-13, 1398/10/23

Ethics committee reference number

IR.SBMU.MSP.REC.1398.862

Health conditions studied

1

Description of health condition studied

Post-pericardiotomy Syndrome

ICD-10 code

I31.9

ICD-10 code description

Disease of pericardium, unspecified

Primary outcomes

1

Description

The occurrence of post-pericardiotomy syndrome (PPS):

Timepoint

2 days before surgery,till 2weeks ,after it

Method of measurement

physical examination-echocardiography PPS confirms when at least two of the following parameters occur simultaneously: 1- Fever: 2-3 weeks post-operative without evidence of systemic or focal infection; 2- Pleuritic chest pain; 3-Friction rub; 4- Evidence of pleural or pericardial effusion

Secondary outcomes

1

Description
The secondary endpoint was the combined rate of disease-related rehospitalization, cardiac tamponade, constrictive pericarditis,and recurrent pericarditis
Timepoint
During first 14 days after cardiac surgery or hospitalization period
Method of measurement
echocardiography-physical examination

Intervention groups

1

Description
Forty-eight hours before surgery, subjects in the intervention group will receive colchicine (Modava pharmaceuticals, Iran) two tablets (equal to 1mg colchicine) every 12 hours for 48 hours and then 1 tablet (equal to 0.5mg) twice daily for two weeks thereafter.
Category
Treatment - Drugs

2

Description
Forty-eight hours before surgery, subjects in the control group will receive identical placebo (Modava pharmaceuticals, Iran) two tablets every 12 hours for 48 hours and then 1 tablet twice a day for two weeks thereafter.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology clinic, Imam Hussein hospital
Full name of responsible person
Masoumeh nazem
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
-
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Shahid Beheshti medical University, aarabi St., Yemen St., chamran Hwy, Velenjak St.
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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
Shahid Beheshti 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Individual data will be shared: Demographic information,post precardiotoy syndrom frequency baseline cardiac function information, concomitant drugs and concomitant illnesses, reported infections.
When the data will become available and for how long
Staring6 months after completion of sampling
To whom data/document is available
The information will be accessible to all categories by reviewing the applicant's eligibility.
Under which criteria data/document could be used
The sending person may include patients, legislators, researchers, university professors and students.
From where data/document is obtainable
Applicants must send their application along with the reason for the need for the study data to the principle investigator's email address. mohamad sistanizad e mail sistanizadm@sbmu.ac.ir
What processes are involved for a request to access data/document
The request is evaluated within 2 weeks by the principal investigator and will be sent to the person or institution requested
Comments