Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical trial of comparison of pleural effusion in Jackson-Pratt drain versus mediastinal chest-tube after coronary artery bypass graft surgery

Protocol summary

Summary

The present study is a randomized, single-blind, non-placebo controlled and single-center clinical trial. The aim of this study is comparison of pleural effusion in Jackson-Pratt drain versus chest-tube after coronary artery bypass graft surgery. Inclusion criteria: Patients 18-75 year-old who are candidates of coronary artery bypass graft (CABG) surgery based on medical history, physical examination, echocardiographic and angiographic findings. Exclusion criteria: Patients who are treating by anti-coagulant drugs. Also patients who are not accessible to be followed up and patients with congenital heart disease will be excluded. First intervention group: After CABG surgery in the operation room, we insert chest tube through left pleural space under the sub-xiphoid region and its size is based on the surgeon idea and patient's condition. Then we put 19-French Jackson drain in mediastinum under the sub-xiphoid region. Second intervention group: After CABG surgery in the operation room, we insert chest tube through left pleural space under the sub-xiphoid region and its size is based on the surgeon idea and patient's condition. Then we put another chest tube in mediastinum under the sub-xiphoid region. The sample size in each group according to the formula that compare two ratios calculated 97 individuals for each group. After admitting the patient in recovery unit or cardiac care unit, total amount of drainage (24 hours after operation) will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701193362N3**
Registration date: **2017-04-02, 1396/01/13**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for reseach, Isfahan University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of pleural effusion in Jackson-Pratt drain versus mediastinal chest-tube after coronary artery bypass graft surgery

Public title

Comparison of pleural effusion in Jackson-Pratt drain versus chest-tube after coronary artery bypass graft

surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 75 years patients; patients according to there examination, medical history and results of echocardiography and angiography, need coronary artery bypass surgery Exclusion criteria: Patients treated with anticoagulant drugs; unable to follow-up; requiring repeated surgery; patients with congenital heart disease

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **194**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done by Random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjerib street, Isfahan

City

Isfahan

Postal code

Approval date

2015-05-28, 1394/03/07

Ethics committee reference number

IR.MUI.REC.1394.3.795

Health conditions studied

1

Description of health condition studied

Pleural effusion

ICD-10 code

J90

ICD-10 code description

Pleural effusion, not elsewhere classified

Primary outcomes

1

Description

Pleural effusion

Timepoint

A month after operation

Method of measurement

Chest X-ray

Secondary outcomes

1

Description

Amount of drainage

Timepoint

24 hours after operation

Method of measurement

Observation

2

Description

Pain score after the operation

Timepoint

2 hours after hospitalization in public sector, 24 hours after operation, 48 hours after operation, at the time of discharge

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: After CABG surgery in the operation room, we insert chest tube through left pleural space under the sub-xiphoid region and its size is based on the surgeon idea and patient's condition. Then we put 19-French Jackson Pratt drain in mediastinum under the sub-xiphoid region.

Category

Treatment - Other

2

Description

Intervention group 2: After CABG surgery in the operation room, we insert chest tube through left pleural space under the sub-xiphoid region and its size is based on the surgeon idea and patient's condition.

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology Clinic of Chamran hospital in Isfahan
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Pejman Pourazari Najafabadi
Street address
Alzahra hospital, Sofe treet, Isfahan
City
Isfahan
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Isfahan University of Medical Sciences
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
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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