

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

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Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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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

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Isfahan

Postal code

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Fax

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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

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Pejman Pourazari Najafabadi

Position

General surgery resident

Other areas of specialty/work

Street address

Hezarjerib street, Isfahan

City

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Mohsen Mirmohammadsadeghi

Position

Cardiovascular Surgery

Other areas of specialty/work

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Person responsible for updating data

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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