

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Mohsen Mir Mohammad Sadeghi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1260 2512

###### Email address

mirmohammadsadeghi@med.mui.ac.ir

##### 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

Isfahan

**Postal code**

**Phone**

+98 31 4263 8075

**Fax**

**Email**

Pejman.po@gmail.com;

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mohsenmirmohammadsadeghi@yahoo.com

**Web page address**

## 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

### Contact

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**Web page address**

## **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*