

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Investigating the effect of removal of chest tube at the end of the exhalation on the severity of pain and pulmonary complications after coronary artery bypass graft surgery.

#### Protocol summary

##### Study aim

Effect of removal of chest tube at the end of the exhalation on the severity of pain and pulmonary complications after coronary artery bypass graft.

##### Design

A clinical trial with a control group, with parallel groups of 60 patients, by random assignment based on binary permutation blocks.

##### Settings and conduct

This study will be done at the Farshchian heart of Hamedan in patients undergoing coronary artery bypass graft. All participants will be taught how to report pain and shortness of breath using the VAS ruler and the scale of the Borg and how to perform valsalva maneuver at the end of the dentia and exhalation. It is described to patients in the tail and exhalation group when the researcher says that they have taken 2-3 deep breaths and by doing a deep tail or undergoing a deep exhalation when the chest tube exits, the amount of pain, shortness of breath expresses the specified intervals and the occurrence of pneumothorax is measured one hour later.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergo cardiopulmonary bypass surgery: Having two chest drainage tubes simultaneously at a distance close to each other.  
Exclusion criteria: Patient dissatisfaction to participate in the study.

##### Intervention groups

The amount of pain, shortness of breath and oxygen saturation of the arterial blood will be measured immediately before - 15 minutes later - 30 minutes later and one hour after the tube is exhausted. The occurrence of pneumothorax will be measured one hour later.

##### Main outcome variables

Severe pain; shortness of breath; pneumothorax; arterial blood oxygen saturation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181031041518N1**

Registration date: **2019-01-23, 1397/11/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

##### Registration date

2019-01-23, 1397/11/03

##### Registrant information

##### Name

Akbar Gohari kamel

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0150

##### Email address

a.gohari@edo.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-30, 1397/09/09

##### Expected recruitment end date

2019-03-29, 1398/01/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating the effect of removal of chest tube at the end of the exhalation on the severity of pain and pulmonary complications after coronary artery bypass graft surgery.

## Public title

The effect of removing the chest tube in the end of expiration on the severity of pain and pulmonary complications after surgery.

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

Awful patients undergoing coronary artery bypass graft surgery by cardiopulmonary bypass method Having two chest drainage chambers at the same distance to each other At least 24 hours have passed since the tubes were imported. Lack of diabetes and neuropathies caused by other diseases Ability to speak and understand Persian language Lack of hearing impairment Having hemodynamic stability (systolic blood pressure greater than 90 mmHg, lack of dangerous dysrhythms)

### Exclusion criteria:

Valve Replacement Surgery Patients undergoing cardiac emergency surgery Patients with diabetes

## Age

From **40 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In the present study, the patients were registered according to the sample size (120) and according to the inclusion criteria, and using the blocking method (using a two-block method, two letters A and B with different permutations we place blocks in blocks and randomly select 60 blocks and assign each block to 2 people) will be assigned to two groups

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

Quasi- Experimental study.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

##### Street address

Blvd fahmideh-Opposite the People's Park-Hamedan University of Medical Sciences-School of Nursing and Midwifery

##### City

Hamedan

##### Province

Hamadan

##### Postal code

65178-38698

#### Approval date

2018-10-12, 1397/07/20

#### Ethics committee reference number

IR.UMSHA.REC.1397.458

## Health conditions studied

### 1

#### Description of health condition studied

Atherosclerotic heart disease

#### ICD-10 code

I25.1

#### ICD-10 code description

Atherosclerotic heart disease of native coronary artery

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

Immediately before, immediately after, 15 minutes and an hour after the chest tube exits.

#### Method of measurement

VAS(Visual Analogue Scale)

## Secondary outcomes

### 1

#### Description

Dyspnea

#### Timepoint

Immediately before, immediately after, 15 minutes and an hour after the chest tube exits.

#### Method of measurement

Borg's Facilitated Criterion.

### 2

#### Description

Amount of spo2

#### **Timepoint**

Immediately before, immediately after, 15 minutes and an hour after the chest tube exits.

#### **Method of measurement**

Monitor device available on the patient's bedside.

### **3**

#### **Description**

Pneumothorax

#### **Timepoint**

An hour after the chest tube exits.

#### **Method of measurement**

Chest X-ray

## **Intervention groups**

### **1**

#### **Description**

The intervention group: In this study, patients are randomly placed under the outflow of the thoracic tube at the end of exhalation. The sampling procedure continues to complete the number of samples. When the researcher said that the patient drew a breath of 2 - 3 deeply breaths and exhaled a deep breath during the outflow of the chest tube (a Valsalva maneuver at the end of exhalation). It receives if it is prescribed for a patient with a narcotic drug. The intensity of pain in the thoracic cavity, the severity of the shortness of breath and the amount of spo2 is measured over the three-time frame: immediately after - 15 minutes and 1 hour after the chest tube pipeline is removed. To measure pneumothorax 1 hour after the departure the chest tube (chest x-ray) and compared with the last CXR of the patient before the extubation of the chest tube by a specialist.

#### **Category**

Treatment - Other

### **2**

#### **Description**

Control group: Includes patients who routinely withdraw from the chest tube at the tail end (performing valsalva maneuver at the tail end). In this group, all the above tutorials are also given, the variables are recorded at the same time but at the end of the tail and compared to the end of the results.

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Heart Hospital of Farshchian Hamedan.

##### **Full name of responsible person**

Akbar Gohari Kamel

#### **Street address**

Shahid Fahmideh Blvd - Farshchian Cardiology and Cardiology Center.

#### **City**

Hamedan

#### **Province**

Hamadan

#### **Postal code**

65178-38698

#### **Phone**

+98 81 3838 1740

#### **Email**

hcvc@umsha.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Mohsen Salavati

##### **Street address**

Fahmideh Blvd- Opposite the People's Park-Hamedan University of Medical Sciences- School of Nursing and Midwifery.

##### **City**

Hamedan

##### **Province**

Hamadan

##### **Postal code**

65178-38698

##### **Phone**

+98 81 3838 0535

##### **Fax**

+98 81 3838 0447

##### **Email**

midnurse@umsha.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences  
**Full name of responsible person**  
Akbar Gohari Kamel  
**Position**  
Nursing Graduate Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Fahmideh Blvd- Opposite the People's Park-Hamedan  
University of Medical Sciences- School of Nursing and  
Midwifery.  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
65178-38698  
**Phone**  
+98 81 3311 5516  
**Email**  
a.gohari@edo.umsha.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Mohsen Salavati  
**Position**  
Master of Science  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Fahmideh Blvd - Opposite the People's Park-Hamedan  
University of Medical Sciences- School of Nursing and  
Midwifery.  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
65178-38698  
**Phone**  
+98 81 3838 0447  
**Email**  
salavatimohsen42@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Akbar Gohari Kamel  
**Position**  
Nursing Graduate Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Fahmideh Blvd - Opposite the People's Park-Hamedan  
University of Medical Sciences- School of Nursing and  
Midwifery.  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
65178-38698  
**Phone**  
+98 81 3311 5516  
**Email**  
a.gohari@edo.umsha.ac.ir

## 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

No - There is not 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 of participants after unidentifiable individuals; and the main implications of the study.

### When the data will become available and for how long

After completing the study.

### To whom data/document is available

Researchers working in scientific institutions

### Under which criteria data/document could be used

Researchers working in scientific institutions

### From where data/document is obtainable

00988133115516

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

Refer to the email: a.gohari@edo.umsha.ac.ir

### Comments