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 dementia 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
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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 theinclusion 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
BIvd 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

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Shahid Fahmideh Blvd - Farshchian Cardiology and Cardiology Center.

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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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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

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Person responsible for scientific inquiries

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Hamedan University of Medical Sciences

Full name of responsible person
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Position
Master of Science

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Other areas of specialty/work
Nursery

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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
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