Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of breathing exercises on respiratory status after coronary artery bypass graft surgery

Protocol summary

Study aim
The effect of breathing exercises on respiratory status after coronary artery bypass graft surgery

Design
A randomized, single-blind, randomized controlled clinical trial on 52 patients was used to randomize the sequence generation software.

Settings and conduct
This study was performed on the respiratory status of patients after coronary artery bypass grafting in Fatemeh Zahra Hospital in Mazandaran. After the necessary explanations to the patients, if they have the consent to participate in the study, they will be placed in the intervention or control group according to the blocking. Respiratory exercises are taught to patients in the intervention group and they perform the exercises after surgery and the control group receives only routine physiotherapy. Finally, a graph is taken from the patients and the incidence of atelectasis and satisfaction with the respiratory status of the patients in both groups are compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: No discharge fraction less than 30% as evidenced by preoperative echocardiography sheet, no chronic respiratory diseases such as asthma and COPD, no history of cardiopulmonary surgery, no lung injury, no history of rib fractures and tubing. Exclusion criteria: Severe hemodynamic abnormalities after surgery, arterial carbon dioxide pressure more than 50 mm Hg, arterial oxygen saturation less than 80%, aortic collapse time more than 150 minutes, pulmonary bypass time more than 240 minutes, intubation more than 24 hours Patient.

Intervention groups
The intervention group included patients who underwent coronary artery bypass grafting and received respiratory training intervention. The comparison group included patients who underwent coronary artery bypass grafting and received only routine expansive physiotherapy.

Main outcome variables
respiratory status; Atelectasis; Monitoring the oxygen supply of patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150916024047N5**
Registration date: **2022-01-04, 1400/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-04, 1400/10/14**
Update count: **0**

Registration date
2022-01-04, 1400/10/14

Registrant information

Name
Hedayat Jafari

Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of breathing exercises on respiratory status after coronary artery bypass graft surgery

Public title
The effect of breathing exercises on respiratory status after coronary artery bypass graft surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old No ejection fraction less than 30% Lack of chronic respiratory diseases such as asthma and COPD No history of heart and lung surgery Not having any lung damage No history of rib fractures Not having any cognitive or neurological disorders No history of head or nose trauma and recurrent sinus infections No history of chemotherapy and use of immunosuppressive drugs in the three months before surgery No BMI more than 40
Exclusion criteria:
Severe hemodynamic disorders after surgery Arterial blood pH less than 7/30 Arterial carbon dioxide pressure more than 50 mm Hg Arterial oxygen saturation is less than 80% despite receiving supplemental oxygen Serum creatinine greater than 3.5 mg / dL Aortic collapse time more than 150 minutes Pulmonary bypass time more than 240 minutes Use of intra-aortic pump balloon during and after surgery Intubation for more than 24 hours Re-transfer of the patient to the operating room and the patient's need for a ventilation-treatment protocol outside the research process
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the limited randomization method of block randomization. The size of all blocks is equal and in this study we will have a trial of two intervention and control groups in 13 blocks of 4 (including 2 participants in the intervention group and 2 participants in the control group). Randomization tool also uses Sampling random sequence generation software that these random sequence generation software in addition to simple randomization are able to generate random sequences by blocking method. Using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding was performed only on a person who evaluates patients' chest x-rays for atelectasis, who does not know which patients are in the intervention group and which patients are in the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of mazandaran University of Medical Sciences
Street address
Golestan Town, Baharestan Blvd., No. 24
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Mazandaran
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Mazandaran
Postal code
3519798363
Approval date
2021-11-03, 1400/08/12
Ethics committee reference number
IR.MAZUMS.REC.1400.562

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft surgery
ICD-10 code
I25.810
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

2

Description of health condition studied
Atelectasis
ICD-10 code
J98.11
ICD-10 code description
Atelectasis

Primary outcomes

1

Description
Respiratory status of patients after coronary artery bypass graft surgery
Timepoint
The second, third, fourth day after surgery
Method of measurement
The arterial blood oxygen saturation of the pulse oximetry device and the intensity of pain are assessed with a 10-point VAS visual criterion.

Secondary outcomes

1

Description
Respiratory status
Timepoint
Periods of respiratory status assessment as a consequence can be stated at the beginning of the study (before the intervention) and the first, second and third days after the start of respiratory training.
Method of measurement
Hearing the lungs of patients

2

Description
Oxygen saturation rate
Timepoint
Arterial blood oxygen saturation on the second, third and fourth day after the start of breathing exercises
Method of measurement
Pulse oximetry

3

Description
VAS standard score
Timepoint
VAS standard score after the end of the respiratory training course
Method of measurement
VAS criteria

Intervention groups

1

Description
Intervention group: The patient is instructed in diaphragmatic breathing and bud lip breathing, and motivational spirometry and effective coughing are performed in combination.The mentioned breathing exercises started one hour after removing the endotracheal tube under the supervision of the researcher or his colleague and will be performed until the 4th day after the surgery. Supervision of the nurse who is fully trained in how to perform exercises and research process, and the results will be recorded in the checklist of respiratory exercises demographic and medical information of patients including age, sex, marital status, education, history of smoking Height, weight, body mass index, and underlying disease (diabetes, hypertension, cardiomyopathy, etc.) will be collected and recorded using a questionnaire.Also, information about the surgical status including the location and number of transplanted vessels, the duration of surgery, the duration of use of the cardiopulmonary pump, the duration of use of artificial ventilation in the ICU and the duration of intubation during the patient care process will be recorded. Due to the fact that some studies have mentioned the maximum incidence of atelectasis in patients undergoing coronary artery bypass graft surgery on the third and fourth days after surgery, and in order not to impose additional burden on patients to undergo double radiography, in this study A chest radiograph will be taken on the day before surgery and at the end of the fourth day after surgery at 9 pm in patients in both groups.Diagnosis of atelectasis is based on the opinion of three radiologists and at least two of them confirm the existence of atelectasis and due to changes including Fisher interlobar displacement, increased density, crowded bronchovascular view, diaphragm in the same side, tracheal displacement, heart The medial side will be affected, the umbilicus will rise in lower lobe atelectasis, compensatory ventilation in other lobes, the hemithorax volume will decrease in the same direction, and the distance between the ribs will decrease. Arterial blood oxygen saturation (SpO2) and respiration rate per minute before induction of anesthesia and after removal of endotracheal tube, on the second, third, fourth day after surgery at 12 noon by pulse oximetry device ALBORZ b9 vital signs monitoring device Will be measured.Lung sound by 3M ™ Littmann® Classic III medical earphone one day before surgery, six hours after surgery every two hours, up to 24 hours after surgery every six hours, the second day every 12 hours and the third and fourth day once At 6 pm, the anesthesiologist will hear and diagnose abnormal sounds (cracking, whistling, extra noise, natural noise reduction, and hoarseness) with the doctor's advice.
Category
Treatment - Other

2

Description
Control group: Control group: Patients in the control group receive routine respiratory physiotherapy and at the end are compared with patients in the intervention group in terms of atelectasis and respiratory status.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Al-Zahra Hospital, Sari
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Sponsors / Funding sources

1

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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Hedayat Jafari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available