Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effect of incentive spirometry and deep breathing exercises on hemodynamic parameters of patients undergoing coronary artery bypass grafting surgery

Protocol summary

Study aim

1Determining and comparing mean score of hemodynamic indices (systolic and diastolic blood pressure, heart rate, arterial oxygen saturation, respiratory rate) before intervention (preoperative) in patients in two groups of respiratory and incentive spirometry;2determining and comparing mean scores of hemodynamic indices on the first, second and third day after surgery in patients in two groups of breathing and incentive spirometry;3Comparing mean score of preoperative hemodynamic indices and the first, second and third postoperative days in respiratory training group;4Comparing mean scores of preoperative hemodynamic indices and first, second and third postoperative day in the incentive spirometry group; 5Comparing mean scores of changes in hemodynamic parameters before surgery and on the first, second and third day after surgery in patients in two groups of respiratory and incentive spirometry.

Design

A clinical trial with two intervention groups, parallel groups, non-double-blinded, and permuted-block randomization

Settings and conduct

Razi Hospital of Birjand, permuted-block randomization

Participants/Inclusion and exclusion criteria

No suffering of cognitive neuromuscular disorders Non-emergency surgery Ability to perform breathing exercises and to use incentive spirometry Willingness to participate in the study Re-surgery due to possible complications Cognitive and neurological complications after surgery Severe hemodynamic disorders (e.g., severe hypo- and hypertension, shock) Severe lung disease (such as chronic obstructive pulmonary disease) Kidney dysfunction

Intervention groups

Deep breathing exercises incentive spirometry

Main outcome variables

Gender; Age; Education; Marital status; Any record of suffering hypertension; Any record of suffering from diabetes; Any record of suffering of hyperlipidemia; Any record of smoking; Hemodynamic indices; Intervention method

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191028045267N1**
Registration date: **2020-03-12, 1398/12/22**
Registration timing: **retrospective**

Last update: **2020-03-12, 1398/12/22**
Update count: **0**

Registration date

2020-03-12, 1398/12/22

Registrant information

Name

Fateme Zerang

Name of organization / entity

Islamic azad university of yazd

Country

Iran (Islamic Republic of)

Phone

+98 56 3234 1503

Email address

fateme.zerang2018@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-14, 1398/10/24

Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of incentive spirometry and deep breathing exercises on hemodynamic parameters of patients undergoing coronary artery bypass grafting surgery

Public title
"Investigating the effect of incentive spirometry on hemodynamic parameters of patients undergoing coronary artery bypass grafting surgery""The effect of deep breathing exercises on hemodynamic parameters of patients undergoing coronary artery bypass grafting surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
No suffering of cognitive neuromuscular disorders Non-emergency surgery Ability to perform breathing exercises and to use incentive spirometry Willingness to participate in the study
Exclusion criteria:
Re-surgery due to possible complications Cognitive and neurological complications after surgery Severe hemodynamic disorders (e.g., severe hypo- and hypertension, shock) Severe lung disease (such as chronic obstructive pulmonary disease) Kidney dysfunction
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups of breathing exercises (n = 20) and incentive spirometry (n = 20) via permuted-block randomization
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Islamic Azad University, Yazd Branch
Street address
Shohaday-e-Gomnam Blvd., Safaeieh D.C., Yazd City, Yazd Province
City
Yazd
Province
Yazd
Postal code
8915813135
Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
IR.IAU.KHUSIF.REC.1398.271

Health conditions studied

1

Description of health condition studied
Patients Candidate for Coronary Artery Bypass Grafting
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Arterial Oxygen Saturation in Two Groups (Incentive Spirometry and Respiratory Exercise)
Timepoint
before surgery, before induction of anesthesia and on the first, second, and third days after surgery,
Method of measurement
A PC-66b pulse oximeter, made in China, was performed

2

Description
Respiratory rate in two groups (incentive spirometry and breathing exercises)
Timepoint
before surgery, before induction of anesthesia and on the first, second, and third days after surgery,
Method of measurement
Observing chest movements in a minute and counting it

3

Description

Systolic and diastolic blood pressure in two groups (incentive spirometry and breathing exercises)

Timepoint

Before surgery, before induction of anesthesia, and on the first, second, and third days after surgery

Method of measurement

As the instructions show, a mercury barometer with an appropriate armband size, while a patient is sitting on a comfortable chair with his/her hand on his/her heart, is measured twice in a 10-15 minute interval and the mean scores is recorded as an his/her blood pressure.

4

Description

Heart rate in two groups (incentive spirometry and breathing exercises)

Timepoint

Before surgery, before induction of anesthesia, and on the first, second, and third days after surgery

Method of measurement

A PC-66b pulse oximeter, made in China, was performed

Secondary outcomes

empty

Intervention groups

1

Description

Control group: incentive spirometry (One day before surgery, patients in the incentive spirometry group were trained on how to use incentive spirometry to ensure that the researcher performed them correctly. Applying a spiral tube to the mouth, he/she inhaled inside the device in a sitting or semi-sitting posture, holding his/her breath for three seconds, and slowly exhaled by removing the device. Patients were asked that each time they increased breathing, they gradually took deeper breaths. This exercise was repeated for 10 deep breaths, every two hours at waking time. These interventions began one hour after the endotracheal tube was removed by the researcher’s supervision or her colleague’s and continued for up to three days after surgery. Hemodynamic parameters were measured and recorded on the first, second, and third days postoperatively.

Category

Prevention

2

Description

Breathing exercises (One day before surgery, patients in the breathing exercises group were trained on how to perform deep scheduled breathing exercises so that the researcher ensures it is performed accurately. Scheduled deep breathing exercises were trained such that a patient is in a sitting or semi-sitting posture, performing slow, deep breathing through the nose, while simultaneously placing his/her hands on the chest to relieve pain and breathing more easily, and after inhalation, holds his/her breath for three seconds. Then he/she exhales through the mouth while the lips and the abdominal muscles are squeezed. He/she must repeat this exercise for a ten times every two hours at waking time. These interventions began one hour after the endotracheal tube was removed by a researcher or her colleague and continued for up to three days after surgery. Hemodynamic parameters were measured and recorded on the first, second, and third days postoperatively.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Fateme Zerang

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No. 18,Yas Ave, Qafari Ave

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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
Islamic Azad University
Proportion provided by this source
50
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
Islamic Azad University
Full name of responsible person
Fateme Zerang
Position
Nurse
Latest degree
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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