

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Street address

No. 18, Yas Ave, Qafari Ave

City

Birjand

Province

South Khorasan

Postal code

9719866838

Phone

+98 56 3234 1503

Email

fatme.zerang2018@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masome Barkhordari

Street address

Shohaday-e-Gomnam Blvd., Safaeieh D.C., Yazd City, Yazd Province

City

Yazd

Province

Yazd

Postal code

8915813135

Phone

+98 35 3821 1391

Email

Barkhordary.m@gmail.com

Web page address

<https://www.iauyazd.ac.ir/>

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

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 18, Yas Ave, Qafari Ave

City

Birjand

Province

South Khorasan

Postal code

9719866838

Phone

+98 56 3234 1503

Email

fateme.zerang2018@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fateme Zerang

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 18, Yas Ave, Qafari Ave

City

Birjand

Province

South Khorasan

Postal code

9719866838

Phone

+98 56 3234 1503

Email

fateme.zerang2018@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fateme Zerang

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 18 ,Yas Ave, Qafari Ave

City

Birjand

Province

South Khorasan

Postal code

9719866838

Phone

+98 56 3234 1503

Email

fateme.zerang2018@gmail.com

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