

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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@gmil.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