# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Investigating the effect of incentive spirometry and breathing exercises on pulmonary complications and the duration of hospitalization of patients undergoing coronary heart transplant surgery

## Protocol summary

**Study aim**
Survey of Effect of Incentive Spirometry and Breathing Exercises on Pulmonary Complications and Length of Hospitalization

**Design**
This is a randomized clinical trial with a parallel design and control group. This randomized study will be conducted on 66 eligible patients undergoing coronary artery surgery. Simple randomization is used for randomization. Three groups are under study, and participants are assigned to two intervention groups and one control group.

**Settings and conduct**
This study, which will be conducted on patients undergoing coronary artery bypass graft surgery at Shahid Sadoughi Hospital in Yazd, is unblinded. Clinical and demographic information will be extracted from the patients' records and recorded before the surgery. They are then taught instructions for deep breathing with an incentive spirometer and how to perform other breathing exercises.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Informed consent; Mechanical ventilation less than 24 hours after surgery Exclusion criteria: History of neuromuscular and cognitive disorders; History of preoperative pulmonary disorders

**Intervention groups**
In the first intervention group, incentive spirometry and breathing exercises will be performed two days before surgery and after surgery until admission to the ICU. In the second intervention group, it will be performed only after the operation until the time of hospitalization in the ICU. It will be performed according to a regular schedule. For both groups, Incentive spirometry will be performed in the form of 10 deep breaths every two hours, in the morning and evening shifts (12 hours) in a sitting or semi-sitting position. In the control group, no intervention will be performed.

**Main outcome variables**
Pneumothorax; Pneumonia; Pleural effusion; Atelectasis; Duration of hospitalization

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20130812014333N259**
Registration date: **2025-08-01, 1404/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-01, 1404/05/10**
Update count: **0**

**Registration date**
2025-08-01, 1404/05/10

**Registrant information**

**Name**
Feizollah Foroughi

**Name of organization / entity**
kermanshah University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-07-06, 1404/04/15

**Expected recruitment end date**
2025-10-07, 1404/07/15

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of incentive spirometry and breathing exercises on pulmonary complications and the duration of hospitalization of patients undergoing coronary heart transplant surgery

**Public title**
Investigating the effect of incentive spirometry and breathing exercises on pulmonary complications
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Informed consent Over 18 years old Mechanical ventilation less than 24 hours after surgery Ability to perform breathing exercises and use incentive spirometry
**Exclusion criteria:**
History of neuromuscular and cognitive disorders History of preoperative pulmonary disorders such as chronic obstructive pulmonary disease (COPD), asthma, severe chest infection, and pulmonary tuberculosis
**Age**
From **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **66**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Using the simple random method. The names of the participants are written on the card. The cards are put into a box that cannot be seen from outside. One of the colleagues of the plan is asked to remove one card from the container at a time. The names of the 22 cards that are selected first are placed in the first intervention group, the second 22 selected cards are placed in the first control group, and the remaining 22 in the second control group
**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 Islamic Azad University, Khorasgan branch
**Street address**
Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street
**City**
Esfahan
**Province**
Isfehan
**Postal code**
8155139998
**Approval date**
2024-11-19, 1403/08/29
**Ethics committee reference number**
IR.IAU.KHUISF.REC.1403.429

## Health conditions studied

### 1

**Description of health condition studied**
Coronary Artery Bypass surgery
**ICD-10 code**
Z95.1
**ICD-10 code description**
Presence of aortocoronary bypass graft

## Primary outcomes

### 1

**Description**
Duration of hospitalization
**Timepoint**
From the time of hospitalization to the day of discharge
**Method of measurement**
Atelectasis

## Secondary outcomes

### 1

**Description**
Atelectasis
**Timepoint**
At the beginning of the study and after the end of the intervention
**Method of measurement**
Using radiography

**2**

**Description**
Pleural effusion
**Timepoint**
At the beginning of the study and after the end of the intervention
**Method of measurement**
Using radiography

**3**

**Description**
Pneumonia
**Timepoint**
At the beginning of the study and after the end of the intervention
**Method of measurement**
Using radiography

**4**

**Description**
Pneumothorax
**Timepoint**
At the beginning of the study and after the end of the intervention
**Method of measurement**
Using radiography

## Intervention groups

**1**

**Description**
In the first intervention group, incentive spirometry and breathing exercises will be performed two days before surgery and after surgery until admission to the ICU. Incentive spirometry will be performed in the form of 10 deep breaths every two hours, in the morning and evening shifts (12 hours) in a sitting or semi-sitting position. After completing inhalation, the patient holds their breath for 3 to 5 seconds and then, by removing the device, exhales slowly through the mouth. Deep breathing exercises include deep inhalation, effective coughing, and diaphragmatic breathing. To cough effectively, the patient coughs five times with maximum strength every hour while awake and rests for 30 seconds after each cough.
**Category**
Treatment - Other

**2**

**Description**
In the second intervention group, it will be performed only after the operation until the time of hospitalization in the ICU. It will be performed according to a regular schedule. Incentive spirometry will be performed in the form of 10 deep breaths every two hours, in the morning and evening shifts (12 hours) in a sitting or semi-sitting position. After completing inhalation, the patient holds their breath for 3 to 5 seconds and then, by removing the device, exhales slowly through the mouth. Deep breathing exercises include deep inhalation, effective coughing, and diaphragmatic breathing. To cough effectively, the patient coughs five times with maximum strength every hour while awake and rests for 30 seconds after each cough.
**Category**
Treatment - Other

**3**

**Description**
In the control group, no intervention will be performed and patients are cared for regularly according to the ward's routine schedule.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Sadoughi Hospital
**Full name of responsible person**
Sina Omidifar
**Street address**
Ebne Sina Street, Shahid Ghandi Blvd.
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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, Khorasgan Branch
**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**
Islamic Azad University, Khorasgan Branch
**Full name of responsible person**
Sina Omidifar
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Master's Degree Student in Nursing
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**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