

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

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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

Isfahan

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

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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
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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