Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Position
Master's Degree Student in Nursing
Latest degree
Bachelor
Other areas of specialty/work
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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