

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of intermittent inspiratory and expiratory incentive spirometry on pulmonary complications of patients undergoing coronary artery bypass graft surgery in patients admitted to intensive care unit of Hamadan heart center in 1397

Protocol summary

Study aim

Determination of the effect of alternating motivational spirometry and exhalation on pulmonary complications of patients undergoing coronary artery bypass graft surgery

Design

Randomized clinical trial with two groups and parallel group design

Settings and conduct

This study is a randomized clinical trial on 66 patients admitted to intensive care units in Hamadan Heart Hospital. In intervention group, patients who will be under alternating motivational inspiration and expiration spirometry will be trained to provide spirometry from 8.AM to 8.PM every two hours up to 10 times, alternately, 2 hours for inspiration and 2 hours for expiratory spirometry. Patients require continuing to do spirometry from the second day until the fifth day after surgery. In control group, no further action will be taken except routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The ability to use a motivational spirometric device; Mechanical ventilation less than 24 hours. Non inclusion criteria: having severe preoperative pulmonary disease (such as chronic obstructive pulmonary disease)

Intervention groups

Intervention group: patients who will be under alternating motivational inspiration and expiration spirometry will be trained to provide spirometry from 8.AM to 8.PM every two hours up to 10 times, alternately, 2 hours for inspiration and 2 hours for expiratory spirometry. Patients require continuing to do spirometry from the second day until the fifth day after surgery. Control group: no further action will be taken except routine care.

Main outcome variables

Atelectasis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N18**

Registration date: **2018-12-14, 1397/09/23**

Registration timing: **prospective**

Last update: **2018-12-14, 1397/09/23**

Update count: **0**

Registration date

2018-12-14, 1397/09/23

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of intermittent inspiratory and expiratory incentive spirometry on pulmonary complications of patients undergoing coronary artery bypass graft surgery in patients admitted to intensive care unit of Hamadan heart center in 1397

Public title
Effect of intermittent inspiratory and expiratory incentive spirometry on pulmonary complications

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Mechanical ventilation less than 24 hours The ability to use a motivational spirometric device
Exclusion criteria:
Having severe preoperative pulmonary disease (such as chronic obstructive pulmonary disease) Severe hemodynamic disorders (such as severe hypertension or shock, shock)

Age
No age limit

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
Samples will be divided into two experimental and control groups based on permutation block randomization method (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly.

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 Hamadan University of Medical Sciences
Street address
Shahid Fahmideh street
City
Hamadan
Province
Hamadan
Postal code
38698-65178

Approval date
2018-11-03, 1397/08/12

Ethics committee reference number
IR.UMSHA.REC.1397.526

Health conditions studied

1

Description of health condition studied
Coronary artery disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Atelectasis

Timepoint
Before and after intervention

Method of measurement
Chest X-ray

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients who will be under alternating motivational inspiration and expiration spirometry will be trained to provide spirometry from 8.AM to 8.PM every two hours up to 10 times, alternately, 2 hours for inspiration and 2 hours for expiratory spirometry. Patients require continuing to do spirometry from the second day until the fifth day after surgery.

Category
Prevention

2

Description

Control group: no further action will be taken except routine care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian hospital

Full name of responsible person

Reza Borzou

Street address

Shahid Fahmideh sreet

City

Hamadan

Province

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Postal code

38698-65178

Phone

+98 81 3838 0535

Email

borzou@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Shahid Fahmideh street

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s-bashirian@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Deputy of research and technology, Hamedan University of Medical Sciences

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

Hamedan University of Medical Sciences

Full name of responsible person

Reza Borzou

Position

Assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Borzou

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Person responsible for updating data

Zahrasabzyani2013@gmail.com

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Sabzyani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Shahid Fahmideh street

City

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Phone

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Email

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

Not applicable

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