Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of a cough assist device on hemodynamic status and oxygen saturation in mechanically ventilated adult patients with pneumonia adimitted to the pulmonary intensive care unit

Protocol summary

Study aim

Determining the effect of a cough assist device on hemodynamic status and oxygen saturation in mechanically ventilated adult patients with pneumonia admitted to the intensive care unit.

Design

This study is a randomized, open-label clinical trial with parallel groups. Patients are randomly assigned in equal numbers to the control and intervention groups. Statistical analyses will be conducted using SPSS software, version 22. the required sample size was calculated to be a total of 72 patients.

Settings and conduct

This study will be conducted in 2025 on patients over 18 years of age with pneumonia who are under mechanical ventilation and hospitalized in the pulmonary intensive care unit of Firuzgar Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria consisted of ICU patients aged ≥18 years; the presence of pneumonia confirmed by chest X-ray or a positive sputum culture; endotracheal intubation with mechanical ventilation for at least 24 hours. Exclusion criteria included patients with diaphragmatic hernia; a history of thoracic surgery; a recent history of upper GI surgery patients with pneumothorax and lack of patient cooperation.

Intervention groups

Patients in the control group will receive only the routine hospital physiotherapy, which includes postural drainage, percussion and clapping, vibration, and coughing techniques, In the intervention group, a cough-assist device will be used. This device delivers positive pressure during inspiration to maximally inflate the lungs, followed by a sudden shift from positive to negative pressure.

Main outcome variables

Arterial oxygen saturation percentage; hemodynamic status; respiratory blood-gas status; volume and quality of patients' pulmonary secretions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251111067960N1**
Registration date: **2025-11-23, 1404/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-23, 1404/09/02**
Update count: **0**

Registration date

2025-11-23, 1404/09/02

Registrant information

Name

Afrouz Kargaran Dehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a cough assist device on hemodynamic status and oxygen saturation in mechanically ventilated adult patients with pneumonia adimitted to the pulmonary intensive care unit

Public title

Clinical effects of mechanical cough assistance in ventilated ICU patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

ICU admitted patiens with at lest 18 years of age Confirmed pneumonia in chest x ray or positive sputum culture Intubated patients who are mechanically ventilated for at least 24 hours Presence of tracheal tube in patient's airway Absence of pneumothorax within a month prior to the study

Exclusion criteria:

Presence diaphragmatic hernia Patients with a history of thorasic surgery Patients with recent history of upper GI surgery Patients with primary neuromuscular disease Patients with pneumothorax in the presence of a chest tube Lack of patient consent

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

patients are randomly and equally assigned to two groups: the control group (recieving routin respiratory physiotherapy) and the intervention group (recieving cough assist therapy). randomization is preformed using computer generated randomization by an individual who is not involved in the study process.

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 comittee of Iran university of medical science

Street address

Iran University of Medical Sciences, Hemmat Expressway, next to Milad Tower, Tehran

City

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Province

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Postal code

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Approval date

2025-07-11, 1404/04/20

Ethics committee reference number

IR.IUMS.FMD.REC.1404.198

Health conditions studied

1

Description of health condition studied

Pneumonia in mechanically ventilated patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Arterial oxygen saturation is measured using a pulse oximeter.

Timepoint

One hour before the intervention and daily for five days afterwards

Method of measurement

Pulse oximeter

2

Description

Hemodynamic status, including heart rate and respiratory rate, is assessed by the ventilator.

Timepoint

One hour before the intervention and daily for five days afterwards

Method of measurement

Ventilator

3

Description

Tidal volume

Timepoint

One hour before the intervention and daily for five days afterwards

Method of measurement

Ventilator

4

Description
Dynamic compliance
Timepoint
One hour before the intervention and daily for five days afterwards
Method of measurement
Ventilator

5

Description
Venous partial pressure of oxygen
Timepoint
One hour before the intervention and daily for five days afterwards
Method of measurement
Venous blood gas lab test

6

Description
Venous partial pressure of carbon dioxide
Timepoint
One hour before the intervention and daily for five days afterwards
Method of measurement
Venous blood gas lab test

7

Description
Respiratory arterial blood gas status in patients before and after treatment.
Timepoint
Before treatment and a day after treatment
Method of measurement
Venous blood gas

8

Description
The volume and quality of patient's pulmonary secretions are assessed during suctioning.
Timepoint
After intervention
Method of measurement
Collection of secretions in a sterile container

9

Description
The duration of mechanical ventilation and intubation, as well as the length of stay in the intensive care unit, are recorded.
Timepoint
Since the start of study
Method of measurement
Recording in patient files

10

Description
The percentage of patients weaned from the ventilator and the percentage of intubated patients successfully extubated.
Timepoint
Since the start of study
Method of measurement
Patients counting

11

Description
Successfully extubating
Timepoint
Since the start of study until 48 hours after extubation
Method of measurement
Recording patient count

Secondary outcomes

empty

Intervention groups

1

Description
Control Group: Patients in the control group received only the routine hospital physiotherapy, which consisted of postural drainage, percussion, vibration, and coughing. These interventions were performed in five different drainage positions for both lungs:1. Prone position with a pillow placed under the abdomen for drainage of the lower lobes. 2–3. right and left lateral decubitus positions with a pillow under the lateral chest wall for the middle lobes.2. Supine position for drainage of the anterior segment of the upper lobes.3. Semi-sitting position leaning forward for drainage of the posterior segments of the upper lobes.Each lung lobe was positioned in its corresponding drainage posture for approximately 5 minutes. During this time, 20–40 percussions were applied to each thoracic lobe. Following percussion, three vibrations were delivered during expiration. At the end of the physiotherapy session, the patient’s secretions were drained and suctioned. Tracheal stimulation (instilling normal saline into the endotracheal tube followed by suctioning) was also performed at the end of each session.Each chest physiotherapy session lasted 30 minutes and was administered once daily. All procedures were carried out by experienced physiotherapists. Additionally, patients were not allowed to receive gavage feeding or nebulization for at least 2 hours before chest physiotherapy.
Category
Rehabilitation

2

Description
Intervention group: In the study group, a cough-assist

device was used. This device applies positive pressure during inspiration to maximize lung volume, followed by a rapid shift from positive to negative pressure, thereby simulating the cough mechanism and facilitating more effective secretion clearance. The device used in this study was the Philips T70 Cough Assist (USA).Initially, the percussor mode of the device was applied for 5 minutes using a frequency of 300–400 Hz, a positive pressure of 20–40 cmH_2O, and an airflow intensity ranging from low to maximum to loosen airway secretions. Subsequently, the device's Auto-Sync mode was used with the following settings: positive pressure 20–40 cmH_2O, negative pressure –20 to –40 cmH_2O, oxygen flow from low to maximum (up to 15 L/min), inspiratory time 1.5 seconds, expiratory time 2.5 seconds, and a pause between inspiration and expiration of 0.3–1 second.In Auto-Sync mode, five inspiratory–expiratory cycles were performed, followed by a 20-second rest, and then the cycles were repeated (3–5 cycles total). This sequence was repeated for 5 minutes. A 1-second pause was provided between each inspiratory–expiratory cycle to allow adequate time for secretion drainage through the endotracheal tube. All patients were positioned in a semi-sitting posture during the mechanical cough-assist procedure. During each mechanical inspiration and expiration, the cough-assist tube was connected to the patient's endotracheal tube.All device parameters within the specified ranges were adjusted based on the patient's vital signs and comfort, taking into account three factors:1. Hemodynamic status2. Patient tolerance3. The amount of sputum and secretionsThe device was used once daily, and these patients did not receive any physiotherapy interventions. The number of sessions was prescribed by the attending physician and performed by trained physiotherapists or nurses. After each session, auscultation of the lungs and verification of ventilator waveforms were performed to confirm the absence of residual secretions.It should be noted that arterial oxygen saturation and hemodynamic parameters—including **RR, HR**, and ventilator-related parameters such as TV and C_dyn —were recorded, assessed, and compared daily for five days, one hour before and after each treatment session. Additionally, respiratory venous blood gas (VBG) parameters, including PCO_2, HCO_3^-, and pH, were recorded, evaluated, and compared before the intervention and daily for five days after the intervention.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Firouzgar Hospital

Full name of responsible person
Afrouz Kargaran Dehkordi

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Afrouz Kargaran Dehkordi

Position
fellowship assistant

Latest degree
Specialist

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data are potentially shareable once the individuals have been fully de-identified.

When the data will become available and for how long
Access begins 3 months after publication

To whom data/document is available
All investigators employed in academic and scientific institutions within the healthcare system.

Under which criteria data/document could be used
Access to the data and documentation is permitted solely for research purposes and for use in subsequent studies. All rights of the researchers and contributors involved in this project are fully reserved.”

From where data/document is obtainable
Firoozgar Hospital, Tehran Iran university of medical science

What processes are involved for a request to access data/document
Submitting a request to the Vice-Chancellor for Research and Technology of Iran University of Medical Sciences to obtain access to the data.

Comments