

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of a cough assist device on hemodynamic status and oxygen saturation in mechanically ventilated adult patients with pneumonia admitted 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 admitted 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 patients with at least 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 thoracic 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 (receiving routine respiratory physiotherapy) and the intervention group (receiving cough assist therapy). randomization is performed 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 committee of Iran university of medical science

Street address

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

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Postal code

1593817415

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 cmH₂O, 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 cmH₂O, negative pressure –20 to –40 cmH₂O, 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 status 2. Patient tolerance 3. The amount of sputum and secretions. The 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 *PCO₂*, *HCO₃⁻*, 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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Person responsible for scientific inquiries

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Latest degree

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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