

# 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  $\geq 18$  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)

##### Phone

+98 38 3333 7754

##### Email address

drkargaran@yahoo.com

##### 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

##### City

Tehran

##### Province

Tehran

##### 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 cmH<sub>2</sub>O, 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<sub>2</sub>O, negative pressure –20 to –40 cmH<sub>2</sub>O, 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<sub>dyn</sub>—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<sub>2</sub>, HCO<sub>3</sub><sup>-</sup>, 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

##### Street address

Beh afarin St. vali asr Sq

##### City

Tehran

##### Province

Tehran

##### Postal code

1593817415

##### Phone

+98 38 3333 7754

##### Email

drkargaran@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Majid Safa

##### Street address

Hemmat Expressway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8862 2703

##### Email

safa.m@iums.ac.ir

#### 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

**Street address**

No.21 yaas complex ali valadi St. beh afarin St. vali asr Sq.

**City**

tehran

**Province**

Tehran

**Postal code**

1593817415

**Phone**

+98 38 3333 7754

**Email**

drkargaran@yahoo.com

## Person responsible for scientific 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

**Street address**

No. 21 Yaas complex, Ali Valadi St. Beh Afarin St. Vali Asr Sq

**City**

Tehran

**Province**

Tehran

**Postal code**

1593817415

**Phone**

+98 38 3333 7754

**Email**

drkargaran@yahoo.com

## Person responsible for updating data

**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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**Province**

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**Postal code**

1593817415

**Phone**

00983933337754

**Email**

drkargaran@yahoo.com

## 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**