

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of high-frequency Chest Wall oscillation (HFCWO) on respiratory outcomes of intubated patients admitted to the internal-surgery intensive care unit

Protocol summary

Study aim

Determining the effect of high-frequency chest wall oscillation in non-intubated patients admitted to the special care department of Erfan Niayesh Hospital on the respiratory outcome

Design

Clinical trial with a control group, parallel, non-blind, randomized, phase 3 on 100 patients (50 people in each group). A simple tap or line randomization method will be used and each client will be placed in the intervention or control group by tossing a coin, tap and line.

Settings and conduct

The study will be conducted in Erfan Niayesh Hospital, Tehran, on non-intubated patients admitted to the general intensive care unit. Adult patients between the ages of 20 and 70 who are not intubated and hospitalized of both genders will be included in the study. The patients will be divided into two groups: both groups will receive the necessary treatments for recovery. are placed specially and the second group will use high frequency chest wall oscillation in addition to standard chest physiotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ICU patients aged 20 to 70 years who are completely bed rested and have systemic weakness and need physical therapy are included in the study. Exclusion criteria: pregnancy, history of chronic lung disease, brain pathology, spinal fracture and pathology, sepsis, pneumonia at the beginning of the study, intubated patients, gastrointestinal bleeding, and lack of consent to enter the study.

Intervention groups

Both groups will receive the necessary treatments for recovery. The first group will undergo standard chest physiotherapy in the intensive care unit, and the second group will use high-frequency chest wall oscillation in addition to standard chest physiotherapy.

Main outcome variables

The respiratory outcome in the present study includes the rate of pneumonia, length of hospitalization and the need for mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230614058485N1**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Zeinab Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 742 0978

Email address

alizadeh.md6010@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of high-frequency Chest Wall oscillation (HFCWO) on respiratory outcomes of intubated patients admitted to the internal-surgery intensive care unit

Public title
Investigating the effect of high-frequency Chest Wall oscillation (HFCWO) on respiratory outcomes of intubated patients admitted to the internal-surgery intensive care unit

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patient aged between 20 to 70 years old, who are complete bed rest with generalized systemic illness and need chest physiotherapy.
Exclusion criteria:
Pregnancy History of chronic pulmonary disease Brain pathology Spine fracture and pathology Sepsis Pneumonia at first step Intubated at first step Gastrointestinal bleeding Lack of consent to enter the study

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple tap or line randomization method will be used and each client will be placed in the intervention or control group by tossing a coin, tap and line.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences.,
Shahid Arabi Street., Shahid Shahriari Square., Tehran
Town

City

Tehran

Province

Tehran

Postal code

19857174 صندوق پستی:

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.SBMU.MSP.REC.1402.103

Health conditions studied

1

Description of health condition studied

Respiratory outcome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pneumonia

Timepoint

During hospitalization in the intensive care unit

Method of measurement

Nosocomial pneumonia or hospital-acquired pneumonia (HAP) criteria

Secondary outcomes

empty

Intervention groups

1

Description

The first group (control) will undergo standard chest physiotherapy in the intensive care unit, and the second group (intervention) will also use HFCWO in addition to standard chest physiotherapy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Erfan Niayesh Hospital

Full name of responsible person

Zeinab Alizadeh

Street address

No 17, Bahar Street., Kabiri Tameh Blvd., West prayer highway., Tehran Town

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Email

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Web page address

https://niayeshhospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Abbas Arabi Street (Parvaneh)., Yemen Street., Shahid Chamran highway.,Tehran

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Email

info@sbmu.ac.ir

Web page address

http://sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zeinab Alizadeh

Position

Critical Care Specialist Assistant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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No. 30, Simin Alley., North Jamalzadeh Street., Tehran Town

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Critical Care Specialist Assistant

Latest degree

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Other areas of specialty/work

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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 non-identifiable information and data of individuals and analyzes will be provided for publication after the end of the study

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions

From where data/document is obtainable

Email: alizadeh.md6010@gmail.com

What processes are involved for a request to access data/document

A valid letter of introduction from a recognized scientific center and university to be sent by email. After inquiring with the introducing center, the requested information will be emailed to that center.

Comments