Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

صندوق پستی: 19857174

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

Peneumonia

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

City
Tehran

Province
Tehran

Postal code
1476919491

Phone
+98 21 4979 6000

Fax
+98 21 4461 0617

Email
info@niayeshhospital.ir

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

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 9781

Fax
+98 21 2243 9981

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

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

City
Tehran

Province
Tehran

Postal code
1418633641

Phone
+98 21 6530 0814

Email
alizadeh.md6010@gmail.com

Person responsible for scientific 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

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

City
Tehran

Province
Tehran

Postal code
1418366341

Phone
+98 21 6530 0814

Email
alizadeh.md6010@gmail.com

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
1418366341

Phone
+98 21 6530 0814

Email
alizadeh.md6010@gmail.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 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