

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effect of chest compression during exhalation with physiotherapy by vibration and percussion methods on weaning index in mechanically ventilated patients

Protocol summary

Study aim

Comparison of the effect of chest compression during exhalation with physical therapy using vibration and percussion methods on isolation indices in patients under mechanical ventilation.

Design

Eligible patients admitted to the special wards of Ayatollah Kashani Hospital, who are under mechanical ventilation for 48 hours. The sample size is 30 people in each group and 60 people in total.

Settings and conduct

Ayatollah Kashani Hospital and in 1401

Participants/Inclusion and exclusion criteria

Inclusion Having an age range of 18 to 70 years Having a tracheal tube No injuries (rib fracture, lung contusion) and chest tube Not undergoing chest surgery Connecting to a ventilator for 48 hours Failure to receive intratracheal suction within one hour before each procedure The mode of ventilator for patients is CPAP Exit : Receiving muscle paralyzing drugs Change in mechanical ventilation device settings

Intervention groups

The first group is subjected to suction without chest compression during exhalation and 3 hours later under suction with chest compression. During exhalation, the researcher applies unilateral pressure in the lower 1/3 of the chest using his hands, and at the end of each exhalation, the pressure is removed from the affected areas of the patient, and the airway secretions are suctioned for each of the studied units at a distance of 3 hours from each other. The day is done. Intervention group 2: First, they are subjected to suction without percussion and vibration physiotherapy, and 3 hours later, they are subjected to suction with percussion and vibration physiotherapy. Vital signs, rapid shallow breathing before the interventions, 5 and 25 minutes after the interventions are recorded in each group, and

then the data are compared for both groups.

Main outcome variables

Indicators of isolation from mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091215002861N18**

Registration date: **2022-12-09, 1401/09/18**

Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**

Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Reza Masoodi

Name of organization / entity

Nursing department, Shahrekord University of Medical Science,

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of chest compression during exhalation with physiotherapy by vibration and percussion methods on weaning index in mechanically ventilated patients

Public title

Investigating chest compressions during exhalation and physiotherapy using percussion and vibration methods on isolation indicators in mechanically ventilated patients

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Having an age range of 18 to 70 years Having a stable hemodynamic status Having a tracheal tube No injuries (rib fracture, lung contusion) and chest tube Not undergoing chest surgery Connecting to a ventilator for 48 hours Failure to receive intratracheal suction within one hour before each procedure The mode of ventilator for patients is CPAP

Exclusion criteria:

Receiving muscle paralyzing drugs during the research period Change in the settings of the mechanical ventilation device for any reason within the time frame of the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly allocated to either an intervention or a control group. Accordingly, a list of participants' names was created and their names were numbered from one to sixty. Then, a random allocation software was used to randomly allocate numbers 1-60 to two groups. The fourth author independently generated allocation sequence and concealed it so that participants, statistical analyst, and the second and the third authors were blind to the sequence. For this purpose, we make our list of Participants and assign each participant a number. Again, we used a random number generator to place each participant in one of the two groups. The following steps were taken to select samples: 1. Preparing a list of all the Participants were enrolled from the databases of these hospitals; 2. A list of all Participants was prepared initially, and then each

member was marked with a specific number (Assigned a sequential number to each Participants (1,2,3...60)). 3. Sample size was calculated at 32 according to the following criteria: ($Z_{1-\alpha/2} = 1.96$, $\alpha = 0.05$, $\beta = 0.1$, $\sigma = 6$ and $d = 5$). 4. The samples were randomly selected by the random number generator software (the participants generated randomly without human interference). However, 30 Participants were recruited to each group (30 Participants) to increase the study power. The fourth author independently generated the allocation sequence and concealed it, so that the participants, the statistical analysts, and the third author were blind to the sequence.

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**

Shahrekord University of Medical Sciences and Health Services

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Nursing department, Nursing and midwifery college, Rahmatie, Shahrekord,

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Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Approval date

2022-11-04, 1401/08/13

Ethics committee reference number

IR.SKUMS.REC.1401.127

Health conditions studied**1****Description of health condition studied**

Comparison of the effect of chest compression during exhalation with physical therapy using vibration and percussion methods on isolation indices in patients under mechanical ventilation.

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Indicators of separation of patients under mechanical ventilation from the ventilator

Timepoint

Indicators of separation of patients under mechanical ventilation from the ventilator

Method of measurement

Before the intervention 5 and 25 minutes after the intervention

Secondary outcomes

1

Description

Assessment of o2sat, rapid shallow breathing, blood pressure, pulse

Timepoint

Before the intervention, 5 and 25 minutes after the intervention

Method of measurement

Checklist that includes assessment of o2sat, rapid shallow breathing, blood pressure, pulse

Intervention groups

1

Description

Intervention group: Compression of the chest during exhalation

Category

Diagnosis

2

Description

Physiotherapy group using vibration and precision method

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان آیت الله کاشانی

Full name of responsible person

دکتر رضا مسعودی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Reza Masoudi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available