

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of the Effect of Manual Hyperinflation and Postural Drainage on Respiratory Indices in Mechanical Ventilation Patients in Intensive Care Units

Protocol summary

Study aim

the effect of manual hyperinflation and postural Drainage on respiratory parameters of mechanical ventilation patients

Design

80 patients were randomized, parallel to the control and intervention groups

Settings and conduct

This study will be done in the Imam Khomeini Hospital in Ilam. Patients will be randomly divided into intervention and control groups and respiratory parameters will be measured before and after the intervention in hospitalized patients.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients older than 18 years and less than 60 years old, positive end expiratory pressure 7.5 cm H₂O, endotracheal Intubation, attached to ventilator in volumetric mod for 48 hours, stable hemodynamic status, no chest tube, chest trauma or: pneumothorax, Embolism, subcutaneous emphysema, burns, no pregnancy, obesity, No use of cardiac pacemaker. Exclusion criteria: receiving mucolytic and cramping drugs, starting, discontinuing or changing bronchodilator expansion agents, changes in mechanical ventilation settings, bronchospasm, Increased intracranial pressure

Intervention groups

Intervention group: first day, respiratory parameters (before routine suctioning and 5, 10 and 25 minutes after Routine suctioning) will be recorded. Then, during the next day before Any time suction, manual dilatation techniques and Postural drainage will be recorded. Then, respiratory parameters (5, 10 and 25 minutes after intervention) will be recorded. control group: In the first 24 hours, patients will be suctioned as needed and respiratory parameters (before routine suction and 5, 10 and 25 minutes after routine suctioning) and during the next day, Required suctioning is performed without

manual dilatation and postural drainage and respiratory parameters (5, 10 and 25 minutes after suctioning) will be recorded.

Main outcome variables

Respiratory indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190124042482N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **retrospective**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Sajad Khodayari

Name of organization / entity

Country

Iran (Islamic Republic of)

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s-khodayari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-19, 1398/03/29

Expected recruitment end date

2019-08-20, 1398/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of Manual Hyperinflation and Postural Drainage on Respiratory Indices in Mechanical Ventilation Patients in Intensive Care Units

Public title

Effect of Hyperinflation and Postural Drainage on Respiratory Indices in Mechanical Ventilation Patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

inclusion criteria: Patients older than 18 years and less than 60 years old, positive end expiratory pressure 7.5 cm H2O, endotracheal Intubation, attached to ventilator in volumetric mod for 48 hours, stable hemodynamic status, no chest tube, no chest trauma or: pneumothorax, Embolism, subcutaneous emphysema, burns, skin grafts and chest repair surgery, pregnancy, obesity, No use of cardiac pacemaker

Exclusion criteria:

Exclusion criteria: receiving mucolytic and diluent drugs (bromoxyn, n-acetylcysteine), cramping drugs, starting, discontinuing or changing bronchodilator expansion agents, changes in mechanical ventilation settings, bronchospasm, Increased intracranial pressure

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Based on inclusion criteria, 80 patients were randomly assigned to the control group (40 cases) and intervention (40cases). Randomization method: block Randomization; randomization unit: Individual; Random layer: not done; Randomization tool: Random sequence generation software (Excel); How to create random sequence: Using random blocks, each block contains 4 people. Assigning a number from 1 to 6 to each block; random allocation hiding: Due to interventions on Unconscious patients, there is no possibility of hiding random assignments.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

dose not have

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Tohid Square, Dr Mirkhani Avenue (East Nursing), Faculty of Nursing and Midwifery, Faculty of Rehabilitation

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.044

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

Ventilation disorder

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

O2saturation

Timepoint

Before, 5, 10 and 25 minutes after suctioning

Method of measurement

Pulse Oximeter

2**Description**

Respiratory rate

Timepoint

Before, 5, 10 and 25 minutes after suctioning

Method of measurement

Ventilator monitor

3

Description

end expiratory co2

Timepoint

Before, 5, 10 and 25 minutes after suctioning

Method of measurement

Capnograph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: first day, respiratory parameters (before routine suctioning and 5, 10 and 25 minutes after Routine suctioning) will be recorded. Then, during the next day before Any time suction, manual dilatation techniques and Postural drainage will be recorded. Then, respiratory parameters (5, 10 and 25 minutes after intervention) will be recorded

Category

Prevention

2

Description

. control group: In the first 24 hours, patients will be suctioned as needed and respiratory parameters (before routine suction and 5, 10 and 25 minutes after routine suctioning) and during the next day, Required suctioning is performed without manual dilatation and postural drainage and respiratory parameters (5, 10 and 25 minutes after suctioning) will be recorded.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Sajad khodayari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

khatereh seylani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The release plan is still unknown

When the data will become available and for how long

The release plan is still unknown

To whom data/document is available

The release plan is still unknown

Under which criteria data/document could be used

The release plan is still unknown

From where data/document is obtainable

The release plan is still unknown

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

The release plan is still unknown

Comments

The release plan is still unknown