

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effect of three passive respiratory exercises (percussion, vibration and manual hyperinflation) methods on cardiopulmonary functions of patient under mechanical ventilation in critical care unit of Besat therapeutic and educational center, Hamadan University of Medical Sciences

Protocol summary

Summary

Objectives: To investigate the effect of passive respiratory exercises on cardiopulmonary function in patient undergoing mechanical ventilation. **Design:** A crossover randomized clinical trial. **Setting and conduct:** The patients in ICU will be enrolled in the study if they fulfill the eligibility criteria. **Participants including major eligibility criteria:** The patients with the following criteria will be included: (a) having intra-tracheal tube or tracheostomy; (b) using ventilator; (c) age of 18 or greater; (d) stable hemodynamic status during last six hours. The patients with any one of the following criteria will be excluded from the study: (a) using dopamine, dobutamine, or nitroglycerine; (b) spinal cord injury; (c) hemorrhage in respiratory system; (d) history of myocardial infarction; (e) pneumothorax or rib fracture; (f) presence of arrhythmia in monitor; (g) respiratory distress such as cyanosis; (h) intra cranial pressure. **Intervention:** Three different intervention will be assessed and compared including: (a) vibration of the back of thorax using vibrator device once for two minutes; (b) percussion of the back of thorax knocking gently one for four minutes; (c) manual hyperinflation using ambo bag to inspire via tracheal tube or thoracotomy, stop for three seconds then expire rapidly relaxing ambo bag. **Main outcome measures:** The outcome of interest is cardiopulmonary function which will be assessed as follows: (a) systolic and diastolic blood pressure per mmHg using monitor device; (b) heart beat per minute using monitor device; (c) arterial oxygen saturation per percent using monitor device; (d) assessing pulmonary compliance per mL/mBar using monitor device; (e) airway resistance per mBar/mL/s using monitor device.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203169014N8**

Registration date: **2012-07-09, 1391/04/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-09, 1391/04/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of three passive respiratory exercises (percussion, vibration and manual hyperinflation) methods on cardiopulmonary functions of patient under mechanical ventilation in critical care unit of Besat therapeutic and educational center, Hamadan University of Medical Sciences

Public title

The effect of passive respiratory exercises on cardiopulmonary function in patient undergoing mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

The patients in ICU will be enrolled in the study if they have the following criteria: (a) having intra-tracheal tube or tracheostomy; (b) using ventilator; (c) age of 18 or greater; (d) stable hemodynamic status during last six hours. The patients with any one of the following criteria will be excluded from the study: (a) using dopamine, dobutamine, or nitroglycerine; (b) spinal cord injury; (c) hemorrhage in respiratory system; (d) history of myocardial infarction; (e) pneumothorax or rib fracture; (f) presence of arrhythmia in monitor; (g) respiratory distress such as cyanosis; (h) intra cranial pressure.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Local Human Subject Review board

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

D/P/16/35/9/1283

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

Patient undergoing mechanical ventilation

ICD-10 code

J95

ICD-10 code description

Postprocedural respiratory disorders, not elsewhere classified

Primary outcomes**1****Description**

The outcome of interest is cardiopulmonary function which will be assessed as follows: (a) systolic and diastolic blood pressure per mmHg using monitor device; (b) heart beat per minute using monitor device; (c) arterial oxygen saturation per percent using monitor device; (d) assessing pulmonary compliance per mL/mBar using monitor device; (e) airway resistance per mBar/mL/s using monitor device.

Timepoint

5 min

Method of measurement

Monitor device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention 1: Vibration of the back of thorax using vibrator device once for two minutes.

Category

Treatment - Devices

2

Description

Intervention 2: Percussion of the back of thorax knocking gentling one for four minutes.

Category

Treatment - Devices

3

Description

Intervention 3: Manual hyperinflation using ambo bag to inspire via tracheal tube or thoracotomy, stop for three seconds then expire rapidly relaxing ambo bag.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Hospital

Full name of responsible person

Dr Ali Beikmoradi

Street address

Department of Internal Medicine and Surgery, Nursing and Midwifery School, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Ahmad Tavilani

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

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Grant name

از محل يك درصد بودجه طرح‌هاي تحقيقاتي دانشگاه

Grant code / Reference number

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

Yes

Title of funding source

Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Research Center for Health Sciences, Department of Epidemiology & Biostatistics

Full name of responsible person

Dr Jalal Poorolajal

Position

MD, PhD, Assistant Professor of Epidemiology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty