Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

A comparative study on the effect of two methods of pressure support setting on the respiratory distress in patients undergoing mechanical ventilation admitted in intensive care units

Protocol summary

Study aim
Determining and comparing the effect of two methods of pressure support setting on the respiratory distress

Design
A double-blind clinical trial with control and test groups (parallel); In this study, minimizing software is used for random allocation. Sample size 56.

Settings and conduct
This study is done at Al-Zahra Hospital with the aim of comparing the effect of two methods of pressure support setting on respiratory distress. In this study, the person who evaluates the results, participants and data analyzer are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patients must be adult; being under mechanical ventilation with tachypnea and shallow breathing (the RSBI more than 105 breaths per minute per liter). Exclusion criteria: chronic obstructive pulmonary disease; acute respiratory distress syndrome, received neuromuscular blocking drug.

Intervention groups
In this study, in the first group (control group), pressure support is adjusted to such an extent that the total number of patient's breaths are less than 30 breaths per minute and the patient's tidal volume is 4-8 ml / kg. In the second group (test group), pressure support is adjusted to such an extent that the patient's rapid shallow breathing index is less than 105 breaths per minute per liter.

Main outcome variables
Respiratory distress observation scale and rapid shallow breathing index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200429047242N1**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**
Update count: **0**

Registration date
2020-06-27, 1399/04/07

Registrant information

Name
Pooneh Barati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-04, 1399/03/15

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study on the effect of two methods of pressure support setting on the respiratory distress in

patients undergoing mechanical ventilation admitted in intensive care units

Public title

A comparative study on the effect of the two methods of pressure support setting on the respiratory distress in patients undergoing mechanical ventilation admitted in intensive care units

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have to be under mechanical ventilation (SPONT mode); The overall respiratory rate of the patients (breath which are delivered by the ventilator and spontaneous breath) must be more than 30 breaths per minute and the tidal volume of patient's breath have to be less than 4-8 ml/kg The rapid shallow breathing index(RSBI) of the patients must be more than 105 breaths per minute per liter Patients must be adult The patient's respiratory distress observation scale must be more than 3

Exclusion criteria:

Chronic obstructive pulmonary disease and acute respiratory distress syndrome Use of neuromuscular blocking drugs

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are divided into two groups using minimization software. Age, sex, body mass index, analgesic use, sedative use, APACHE IV index rate and PEEP rate are given to minimization software to divide patients into two groups. Minimization (or Minimizer) is the name of a software used to divide samples among groups in clinical trials. In research projects, there are always variables that may affect the accuracy of the study (confounder variables); By entering these variables in this software, the variables are distributed among the research groups in such a way that there is the least difference between the groups, and for this reason, this method is preferable to the randomization method.This software has been installed on the website of Isfahan University of Medical Sciences at http://rct.mui.ac.ir/q/index.php; In this research we will use this website too.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind because in this study, the researcher (data collector and outcome assessor) first fill in the first part of the questionnaire and then the researcher's coworker (clinical caregiver; anesthesiologist) enters the data into the minimization software and then he sets pressure support by RSBI or " tidal volume and respiratory rate" method. The researcher fills the second and third parts of the questionnaire 15 and 30 minutes after setting the pressure support. The participant (patient), the researcher (data collector and outcome assessor) and the data analyst are not aware of how the samples are categorized. The draft of the article is prepared by the researcher too.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Nursing and midwifery faculty, Isfahan university of medical sciences, Hezar Jerib street

City

Isfahan

Province

Isfehan

Postal code

8174673465

Approval date

2020-04-15, 1399/01/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.040

Health conditions studied

1

Description of health condition studied

patients under mechanical ventilation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

signs and indicators of respiratory distress

Timepoint

before setting the pressure support, 15 and 30 minutes after setting it

Method of measurement

respiratory distress observation scale, rapid shallow breathing index(RSBI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, pressure support is adjusted to the extent that the patient's rapid shallow breathing index is less than 105 breaths per minute per liter, because when this index is less than 105, the patient does not have rapid and shallow breathing (respiratory distress) and this means that the pressure support is properly adjusted for the patient.

Category

Treatment - Devices

2

Description

Control group: In this group, the adjustment of pressure support is based on tidal volume and number of breaths. Pressure support is adjusted to the extent that the patient's breathing rate is less than 30 and his or her tidal volume is more than 4-8 ml / kg, because in this case the patient does not have respiratory distress; this means that the patient's pressure support is set correctly.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra Hospital

Full name of responsible person

Somayeh Ghafari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Somayeh Ghafari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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