

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of positive end expiratory pressure (PEEP) changes on central venous pressure in hospitalized patients in Intensive care unit

Protocol summary

Study aim

Investigating the effect of changes in the positive end-expiratory pressure on central venous pressure

Design

Semi-experimental clinical trial. Patients over 18 years of age with CV line who are under mechanical respiration and have stable vital signs will enter the study. The number of samples will be based on the coefficient correlation sample size formula equal to 62 which increased to 70 to guarantee. The sampling method of this study is consecutive. Randomization won't be used

Settings and conduct

This study will be done at Intensive care unit of Poursina hospital in Rasht. In addition, the study will be performed double blind in which all measurements will be done by one person (emergency medicine resident) who is not involved in the study and is not aware of PEEP's condition. Meanwhile, patients won't be aware of the events due to intubation and receiving anesthesia drugs.

Participants/Inclusion and exclusion criteria

Inclusion criterion: All patients over 18 years of age admitted with CV line and stable vital signs. Non-inclusion Criteria: Patients need to receive more than 200mL of fluid per hour; Patients with auto PEEP; Patients need PEEP more than 10cmH₂O; The dissatisfaction of first-degree relatives of the patient; Any contraindications to increase PEEP.

Intervention groups

There is only one intervention group. Intubated patients connected to a ventilator who have a right subclavian vein catheter with one type of sedation drug and one type of ventilator settings have entered the study. Central venous pressure (CVP) in peep 3, 5 and 7 will be measured with a CVP ruler by one person (emergency medicine resident who is not in the study and does not know the peep number (for blinding)).

Main outcome variables

Central venous pressure (CVP) in different PEEPs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191211045700N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **retrospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

mahdi zia ziabari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3322 2444

Email address

drziabari@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of positive end expiratory pressure (PEEP) changes on central venous pressure in hospitalized patients in Intensive care unit

Public title

The effect of positive end expiratory pressure (PEEP) changes on central venous pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being at the age of 18 years and over Intubated patients connected to the ventilator Patients with right subclavian CV line Stable vital sign

Exclusion criteria:

Patients who need more than 200 cc serum per hour Patients with auto peep Patients who need more than 10 cmH₂O peep Sudden changes in vital sign with peep change lung injury Chronic obstructive pulmonary diseases (COPD) Asthma Valve disorders Acute respiratory distress syndrome (ARDS) BMI>30 Dissatisfaction of relatives

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 70

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Supervisor has no information about peep and just measures CVP. Patients are not aware of the events due to intubation and receiving anesthesia drugs.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Namjoo street

City

Rasht

Province

Guilan

Postal code

2008-7284

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.GUMS.REC.1398.320

Health conditions studied

1

Description of health condition studied

Patients who are over 18 years old with CV line, and are under mechanical respiration with stable vital signs and are hospitalized in ICU ward of Poursina Hospital in Rasht. Patients with various diseases such as trauma, CVA, sepsis and ... are hospitalized in this ward.

ICD-10 code

Z99.11

ICD-10 code description

Dependence on respirator [ventilator] status

Primary outcomes

1

Description

Central venous pressure (CVP)

Timepoint

After 10 minutes being on peep 3, 5 and 7

Method of measurement

CV line

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intubated patients connected to a ventilator with one type of sedation drug and one type of ventilator settings will enter the study. Patient demographics will be recorded in pre-designed checklists. To reduce the incidence of error, patients with a right subclavian vein catheter will be included in the study. Patients' CVP will be measured after ten minutes in peep 3, 5, 7. Then the CVP number and its changes in the three measured pipes (3, 5 and 7) will be recorded in the checklists. Also, all measurements will be performed by one person (emergency medicine resident who is not in the study and does not know Peep status (for blindness)) and at the level of par with the sternum angle and with a special CVP ruler. Then the changes of CVP in different pipes (peep from 3 to 5, 5 to 7 and also 3 to 7)

will be examined and will be analyzed by statistical tests.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Poursina hospital

Full name of responsible person

Seyyed Mahdi Zia Ziabari

Street address

Poursina hospital, Namjoo street

City

Rasht

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41937-13194

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poursina_pr@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Seyyed Mahdi Zia Ziabari

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Phone

+98 13 3332 2444

Email

poursina_pr@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Seyyed Mahdi Zia Ziabari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Poursina hospital, Poursina intersection

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Guilan

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Email

drziabari@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Seyyed Mahdi Zia Ziabari

Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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

The data about the main outcome will be given to the applicants after deleting the patients' personal information in SPSS file format.

When the data will become available and for how long

Three months after finishing of study.

To whom data/document is available

The researchers in medical centers

Under which criteria data/document could be used

To compare with other studies and also for estimating sample size.

From where data/document is obtainable

To receive more information, be in contact with Dr. Seyed Mehdi Zia Ziabari via drziabari@gums.ac.ir mail address.

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

A request letter and information related to researcher including his/her ID card would send them to the mentioned e-mail address. The information will be sent within 15 days after receiving the request.

Comments