

# 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 10cmH<sub>2</sub>O; 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 cmH<sub>2</sub>O 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

**Province**

Guilan

**Postal code**

41937-13194

**Phone**

+98 13 3332 2444

**Email**

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

**Street address**

Poursina hospital, Namjoo street

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**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

**Street address**

Poursina hospital, Poursina intersection

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713194

**Phone**

+98 13 3333 9842

**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

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Poursina hospital, Poursina Intersection

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

Rasht University of Medical Sciences

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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**