

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of positive end expiratory pressure on internal jugular vein collapsibility index in mechanically ventilated patients in intensive care unit.

Protocol summary

Study aim

Evaluation of the three different positive end expiratory positive pressure effect on internal jugular vein collapsibility index in mechanically ventilated patients

Design

30 patients will be included in this double blind clinical trial. A person will change the set of ventilators and one another will measure the internal jugular vein collapsibility index. In this study, randomization and trial phase is not applicable. All patients are in one group. Ventilator changes is applied three times in each patient.

Settings and conduct

This study is done on 30 patients over 18 years of age and connect to ventilator. All patients are in one group and end expiratory positive pressure of ventilator changes with 0, 5 and 10 cm H₂O will be applied three times in each patient. This study is a double blind clinical trial. A person will change the set of ventilators and one another will measure the internal jugular vein collapsibility index. In this study, randomization and trial phase is not applicable.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years. Exclusion criteria: Cardiovascular and pulmonary disease; Cervical collar or neck dressing

Intervention groups

Patients are placed on three end expiratory positive pressure of 0, 5 and 10 cm H₂O. Internal jugular collapsibility index is measured in all three tidal volumes. After the fluid therapy, the above steps will be repeated and ventilator changes is applied three times before and after fluid therapy in each patient.

Main outcome variables

Internal jugular vein collapsibility index in end expiratory positive pressure of 0, 5 and 10 cm H₂O

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005363N13**

Registration date: **2019-06-13, 1398/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

Taraneh Naghibi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 2865

Email address

tnaghibi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-08-11, 1398/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of positive end expiratory pressure on internal jugular vein collapsibility index in mechanically ventilated patients in intensive care unit.

Public title

The effect of positive end expiratory pressure on internal jugular vein collapsibility index

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years

Exclusion criteria:

Cardiovascular and pulmonary diseases Sepsis Neck collar or neck dressing

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **3**

Internal jugular vein collapsibility index in various positive end expiratory pressure

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients are not aware of the treatment group due to the decreased level of consciousness. The researcher who studies the variables, does not know the intervention and change of ventilator setting is done by another person.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical

Sciences

Street address

Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi square

City

Zanjan

Province

Zanjan

Postal code

4513994945

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.ZUMS.REC.1398.025

Health conditions studied

1

Description of health condition studied

Evaluation of internal jugular vein collapsibility index in three different of positive end expiratory pressure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Internal jugular collapsibility index in positive end expiratory pressure of 0 cm H2O

Timepoint

5 minutes after selecting the positive end expiratory pressure of 0 cm H2O

Method of measurement

ultrasound system (eZono 3000)

2

Description

Internal jugular collapsibility index in positive end expiratory pressure of 5 cm H2O

Timepoint

5 minutes after selecting the positive end expiratory pressure of 5 cm H2O

Method of measurement

ultrasound system (eZono 3000)

3

Description

Internal jugular collapsibility index in positive end expiratory pressure of 10 cm H2O

Timepoint

5 minutes after selecting the positive end expiratory pressure of 10 cm H2O

Method of measurement

ultrasound system (eZono 3000)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients will be placed on the ventilator under the following conditions. SIMV: TV= 8 cc/Kg, RR=10, PEEP=0, Fio2=50%. Then positive end expiratory pressure of ventilator will be changed to 5 and 10 cm H2O and the internal jugular collapsibility index will be measured after each conditions.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Mosavi Hospital

Full name of responsible person

Taraneh Naghibi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan 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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Hamid Kafili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Taraneh Naghibi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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