

# 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 H<sub>2</sub>O 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 H<sub>2</sub>O. 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 H<sub>2</sub>O

#### 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

#### Street address

Gavazang Road

#### City

Zanjan

#### Province

Zanjan

#### Postal code

4513994945

#### Phone

+98 24 3313 1559

#### Email

tnaghibi@zums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Zanjan University of Medical Sciences

#### Full name of responsible person

Dr Ali Reza Shoghli

#### Street address

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

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#### Postal code

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#### Phone

+98 24 3342 0677

#### Email

shoghli@zums.ac.ir

### 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

#### Street address

Mosavi Hospital, Gavazang Road

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#### Province

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+98 24833131559

#### Email

hkafili55@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Zanjan University of Medical Sciences

#### Full name of responsible person

Taraneh Naghibi

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Taraneh Naghibi  
**Position**  
Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
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**Province**  
Zanjan

**Postal code**  
4513994945  
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**Email**  
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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