

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Evaluation of pressure- and volume-controlled ventilation on internal jugular vein collapsibility index as a predictor of fluid responsiveness in hypovolemic mechanically ventilated patients in intensive care unit.

#### Protocol summary

##### Study aim

Evaluation of pressure- and volume-controlled ventilation on internal jugular vein collapsibility index as a predictor of fluid responsiveness in hypovolemic mechanically ventilated patients in intensive care unit.

##### Design

60 patients will be included in this double blind clinical trial. Patients will be randomly divided into two groups. The set of ventilators will be changed by a personnel and the internal jugular vein collapsibility index will be measured by another one. In this study, trial phase is not applicable.

##### Settings and conduct

This study will be conducted on patients underwent mechanical ventilation in intensive care units. The patients will be allocated to 1 of the 2 groups according to a randomization code list in a computer program. Patients and researchers are not aware of the treatment group. Patients are not aware of the treatment group due to the decreased level of consciousness. A person will change the set of ventilators and one another will measure the internal jugular vein collapsibility index.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Hypovolemic patients; aged over 18 years. Exclusion criteria: Cardiovascular and pulmonary disease; Cervical collar or neck dressing; Internal jugular collapsibility index less than 18%

##### Intervention groups

Hypovolemic patients will be divided into two groups. patients in the first group will be placed on the volume-controlled ventilation and in the second group will be placed on the pressure-controlled ventilation. The internal jugular collapsibility index will be measured before and after fluid therapy.

##### Main outcome variables

Internal jugular vein collapsibility index in pressure- and volume-controlled ventilation before and after fluid

therapy.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101211005363N12**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

##### Registration date

2019-04-29, 1398/02/09

##### 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

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of pressure- and volume-controlled ventilation on internal jugular vein collapsibility index as a predictor of fluid responsiveness in hypovolemic mechanically ventilated patients in intensive care unit.

**Public title**  
Evaluation of pressure- and volume-controlled ventilation on internal jugular vein collapsibility index in hypovolemic patients.

**Purpose**  
Diagnostic

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Hypovolemic patients 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: **60**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Internal jugular collapsibility index is measured before and after fluid therapy in each patient.

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients will be allocated to 1 of the 2 groups according to a randomization code list by a computer program.

**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 group of study and change of ventilator setting is done by another person.

**Placebo**  
Not used

**Assignment**  
Parallel

**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**

2017-10-16, 1396/07/24

**Ethics committee reference number**

IR.ZUMS.REC.1396.179

**Health conditions studied**

1

**Description of health condition studied**

Hypovolemia

**ICD-10 code**

E86.1

**ICD-10 code description**

Hypovolemia

**Primary outcomes**

1

**Description**

Internal jugular collapsibility index in volume mode before fluid therapy

**Timepoint**

5 minutes after selecting the volume mode

**Method of measurement**

ultrasound system (eZono 3000)

2

**Description**

Internal jugular collapsibility index in pressure mode before fluid therapy

**Timepoint**

5 minutes after selecting the pressure mode

**Method of measurement**

ultrasound system (eZono 3000)

3

**Description**

Internal jugular collapsibility index in volume mode after fluid therapy

**Timepoint**

5 minutes after fluid therapy

**Method of measurement**

ultrasound system (eZono 3000)

tnaghibi@zums.ac.ir

**4****Description**

Internal jugular collapsibility index in pressure mode after fluid therapy.

**Timepoint**

5 minutes after fluid therapy

**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. CMV: TV= 8 cc/Kg, PEEP=5, Fio2=50%, and the internal jugular collapsibility index will be measured before and after fluid therapy.

**Category**

Diagnosis

**2****Description**

Intervention group: The patients will be placed on the ventilator under the following conditions. PCV and inspiratory pressure will be adjusted so that the tidal volume will be kept at 8 cc / Kg and the current volume does not exceed 900 Cc and the maximum pressure will be less than 30 centimeters of water.

**Category**

Diagnosis

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mosavi Hospital

**Full name of responsible person**

Taraneh Naghibi

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Gavazang Road

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Zanjan

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**Postal code**

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**Phone**

+98 24 3313 1559

**Email****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Alireza shoghli

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

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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**

sajad Mohammadi

**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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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Position**

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**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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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