

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)

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

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 Alireza shoghli

Street address

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

City

Zanjan

Province

Zanjan

Postal code

4513994945

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

sajad Mohammadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Gavazang Road, Mosavie Hospital

City

Zanjan

Province

Zanjan

Postal code
4513994945
Phone
+98 24 3313 1559
Email
sajad.mohammadi.6182@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
Street address
Mosavi Hospital, Gavazang Road
City
Zanjan
Province
Zanjan
Postal code
4513994945
Phone
+98 243313559
Email
tnaghibi@zums.ac.ir

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
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Mosavi Hospital, Gavazang Road
City
Zanjan
Province
Zanjan
Postal code
4513994945
Phone
+98 24 3313 1559
Email
tnaghibi@zums.ac.ir

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