Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

Evaluation of three different tidal volume effect on internal jugular vein collapsibility index to predict fluid responsiveness in hypovolemic mechanically ventilated patients in intensive care unit.

Protocol summary

Study aim

Evaluation of three different tidal volumes effect on internal jugular vein collapsibility index to predict fluid responsiveness in hypovolemic 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 before and after fluid therapy in each patient.

Settings and conduct

This study is done on 30 hypovolemic patients over 18 years of age and connect to ventilator. All patients are in one group and ventilator changes with 8, 10 and 12 tidal volume is applied three times before and after fluid therapy in each patient.This study is a double blind clinical trial. A person change the set of ventilators and one another measure the internal jugular vein collapsibility index. In this study, randomization and trial phase is not applicable.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hypovolymic 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

Hypovolymic patients are placed on three tidal volumes of 8, 10 and 12 cc per kg of weight.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 tidal volume of 8; 10; 12 cc per kg of weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005363N11**
Registration date: **2019-04-07, 1398/01/18**
Registration timing: **retrospective**

Last update: **2019-04-07, 1398/01/18**
Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Taraneh Naghibi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of three different tidal volume effect on internal jugular vein collapsibility index to predict fluid responsiveness in hypovolemic mechanically ventilated patients in intensive care unit.

Public title

Evaluation of three different tidal volumes effect on internal jugular vein collapsibility index in hypovolemic mechanically ventilated 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

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **6**

internal jugular vein collapsibility index in various tidal volumes before and after treatment with liquid

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

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

2017-11-22, 1396/09/01

Ethics committee reference number

IR.ZUMS.REC.1396.208

Health conditions studied

1

Description of health condition studied

Hypovolemia

ICD-10 code

E86

ICD-10 code description

Hypovolemia

Primary outcomes

1

Description

Internal jugular collapsibility index in tidal volume of 8 cc per kg

Timepoint

5 minutes after selecting the tidal volume of 8 cc per kilogram

Method of measurement

ultrasound system (eZono 3000)

2

Description

Internal jugular collapsibility index in tidal volume of 10 cc per kg of weight

Timepoint

5 minutes after selecting the tidal volume of 10 cc per kilogram

Method of measurement

ultrasound system (eZono 3000)

3

Description

Internal jugular collapsibility index in tidal volume of 12 cc per kg

Timepoint

5 minutes after selecting the tidal volume of 12 cc per kilogram

Method of measurement

ultrasound system (eZono 3000)

4

Description

Internal jugular collapsibility index in tidal volume of 8 cc

per kg after fluid therapy.

Timepoint

5 minutes after selecting the tidal volume of 8 cc per kilogram

Method of measurement

ultrasound system (eZono 3000)

5

Description

Internal jugular collapsibility index in tidal volume of 10 cc per kg after fluid therapy.

Timepoint

5 minutes after selecting the tidal volume of 10 cc per kilogram

Method of measurement

ultrasound system (eZono 3000)

6

Description

Internal jugular collapsibility index in tidal volume of 12 cc per kg after fluid therapy.

Timepoint

5 minutes after selecting the tidal volume of 12 cc per kilogram

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=5, Fio2=50%. Then tidal volume of ventilator will be changed to 10 and 12 cc/kg and the internal jugular colapsibility index will be measured after each conditions. After fluid therapy internal jugular colapsibility index will be measured again in 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

Dr Ali Reza Shoghli

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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

Fatemeh Safavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology
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Person responsible for scientific inquiries

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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