Clinical Trial Protocol
Iranian Registry of Clinical Trials
09 Nov 2023

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)
Phone
+98 24 3347 2865
Email address
tnaghibi@zums.ac.ir

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
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

**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

**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

**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)

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<table>
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<tr>
<th>5</th>
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<tbody>
<tr>
<td><strong>Description</strong></td>
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<tr>
<td>Internal jugular collapsibility index in tidal volume of 10 cc per kg after fluid therapy.</td>
</tr>
<tr>
<td><strong>Timepoint</strong></td>
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<td><strong>Method of measurement</strong></td>
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<td>ultrasound system (eZono 3000)</td>
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<tr>
<td><strong>Description</strong></td>
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<td><strong>Method of measurement</strong></td>
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**Secondary outcomes**
empty

**Intervention groups**

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<tr>
<td><strong>Description</strong></td>
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<td>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 collapsibility index will be measured after each conditions. After fluid therapy internal jugular collapsibility index will be measured again in each conditions.</td>
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**Category**
Diagnosis

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**Recruitment centers**

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<tr>
<td><strong>Recruitment center</strong></td>
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<td>Name of recruitment center</td>
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<tr>
<td>Mosavi Hospital</td>
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<tr>
<td>Full name of responsible person</td>
</tr>
<tr>
<td>Taraneh Naghibi</td>
</tr>
<tr>
<td>Street address</td>
</tr>
<tr>
<td>Gavazang Road</td>
</tr>
<tr>
<td>City</td>
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<tr>
<td>Zanjan</td>
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**Province**
Zanjan

**Postal code**
4513994945

**Phone**
+98 24 3313 1559

**Email**
tnaghibi@zums.ac.ir

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**Sponsors / Funding sources**

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<tr>
<td><strong>Sponsor</strong></td>
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<td>Name of organization / entity</td>
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<tr>
<td>Zanjan University of Medical Sciences</td>
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<tr>
<td>Full name of responsible person</td>
</tr>
<tr>
<td>Dr Ali Reza Shoghli</td>
</tr>
<tr>
<td>Street address</td>
</tr>
<tr>
<td>Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi square</td>
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<tr>
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<td>Zanjan</td>
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<td>4513994945</td>
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<tr>
<td>Phone</td>
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<tr>
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</tr>
<tr>
<td>Email</td>
</tr>
<tr>
<td><a href="mailto:shoghli@zums.ac.ir">shoghli@zums.ac.ir</a></td>
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**Grant name**
empty

**Grant code / Reference number**
empty

**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**
empty

**Type of organization providing the funding**
Academic

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**Person responsible for general inquiries**

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<tr>
<td>Name of organization / entity</td>
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<tr>
<td>Zanjan University of Medical Sciences</td>
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<tr>
<td>Full name of responsible person</td>
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<tr>
<td>Fatemeh Safavi</td>
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<tr>
<td>Position</td>
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<tr>
<td>Resident</td>
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<tr>
<td>Latest degree</td>
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<tr>
<td>Medical doctor</td>
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<td>Other areas of specialty/work</td>
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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
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Province
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Postal code
4513994945
Phone
+92 48 33131559
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