Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of airway pressure release ventilation on intracranial pressure and oxygenation of patients with traumatic brain injuries

Protocol summary

Summary

Objective: To determine the effect of APRV on intracranial pressure and cerebral oxygenation of patients with traumatic brain injuries. Study design: randomized clinical trial in two groups. Study population: patients with traumatic brain injury. Inclusion criteria: age between 18 and 70 years; patient with traumatic brain injury who are under intubation and mechanical ventilation with SIMV mode; stable hemodynamic (MAP > 70 mm Hg at least 30 minutes before the start of the study); Glasgow Coma Scale <9. Exclusion criteria: unstable hemodynamic (MAP <70); CPP <60 mm Hg; intracranial pressure > 25 mmHg. Sample size: 20 patients in each group. Intervention: in Intervention group, apply the APRV mode for up to half an hour, compared with SIMV in control group and then variables (ICP, CPP, PaO2, Paco2, P/F ratio, MAP) are measured. Expected outcome: APRV can be safely used in TBI patients without increasing ICP and it improve hypoxemia.

General information

Acronym

Airway Pressure Release Ventilation

IRCT registration information

IRCT registration number: **IRCT2015070623104N1**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Aliyeh Pasandideh

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of airway pressure release ventilation on intracranial pressure and oxygenation of patients with traumatic brain injuries

Public title

Effect of mechanical ventilation on intracranial pressure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 70 years; traumatic brain injuries who are intubated and under mechanical ventilation with SIMV mode; stable hemodynamic (MAP more than 70 mm Hg for at least 30 minutes before the start of the study); Glasgow Coma Scale <9 ; no history of chronic obstructive pulmonary disease (COPD); ratio of arterial oxygen to inspired

oxygen fraction <400; having intraventricular catheter for ICP monitoring; ICP > 10 mm Hg. Exclusion criteria: unstable hemodynamic (MAP <70); CPP <60 mmHg; ICP > 25 mmHg; pneumothorax

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Quraishi building, Daneshgah street, Mashhad

City
Mashhad

Postal code

Approval date
2015-07-04, 1394/04/13

Ethics committee reference number
IR.MUMS.IEC.1394.249

Health conditions studied

1

Description of health condition studied
traumatic brain injuries

ICD-10 code
s06.2, s06

ICD-10 code description
Other intracranial injuries, Intracranial injury with prolonged coma,Traumatic subarachnoid haemorrhage,Traumatic subdural haemorrhage,Diffuse brain injury,Focal brain injury,Epidural haemorrhage,

Primary outcomes

1

Description
Intracranial pressure

Timepoint
Before and half an hour after the intervention

Method of measurement
Intraventricular catheter -mmHg

2

Description
Pressure of arterial oxygen

Timepoint
Before and half an hour after the intervention

Method of measurement
mmHg

3

Description
Arterial oxygen saturation

Timepoint
Before and half an hour after the intervention

Method of measurement
Pulseoxymetry- percent

4

Description
Ratio of arterial oxygen to inspired oxygen fraction

Timepoint
Before and half an hour after the intervention

Method of measurement
number

Secondary outcomes

1

Description
Mean arterial pressure

Timepoint
Before and after half an hour the intervention.

Method of measurement
Barometer- mmHg

2

Description
Cerebral perfusion pressure

Timepoint
Before and after half an hour the intervention

Method of measurement
Calculation formula- mmHg

Intervention groups

1

Description
Intervention of this research is a ventilation mode that is called Airway Pressure Release Ventilation that applied for half an hour. This is an inverse ratio mode that airway pressure of patient, between high pressure and low pressure is fluctuated. In this intervention, the duration of high pressure is 5 second and duration of low pressure is 1 second. The high-level pressure based on the mean airway pressure of patient.
Category
Other

2

Description
In the control group patients are ventilated with SIMV mode for half an hour.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Trauma Center of Mashhad(Shahid Kamiyab hospital)- Neurosurgery Intensive Care Unit
Full name of responsible person
Aliyeh Pasandideh
Street address
Fadaeyan Eslam street, Mashhad
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences, research assisstance
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Quraishi building, Daneshgah Street, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences, research assisstance
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty