

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 assistance

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Quraishi building, Daneshgah Street, Mashhad

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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 assistance

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

Mashhad University of Medical Sciences

Full name of responsible person

Javad Malekzadeh

Position

master of nursing science

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Javad malekzadeh

Position

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Other areas of specialty/work

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Person responsible for updating data

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Aliyeh pasandideh

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student

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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