Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect Comparison of synchronized intermittent mandatory ventilation and airway pressure release ventilation in oxynation and hemodynamic parameters in patients with head trauma.

Protocol summary

Summary

Objective: To determine the effect of APRV on oxynation and hemodynamic of patients with traumatic brain injuries. This study is a clinical trial with a crossover design and subjects will be allocated into two groups according to the table of random numbers. Study population: patients with traumatic brain injury. Inclusion criteria: age between 15 and 60 years; patients with traumatic brain injury who are intubated and are under mechanical ventilation with SIMV mode; stable hemodynamic (MAP > 70 mm Hg); Glasgow Coma Scale <9. Exclusion criteria: unstable hemodynamic (MAP <70), need to CPR. Sample size: 36 patients in each group. Intervention of this research is a ventilation mode called Airway Pressure Release Ventilation that will be applied using ventilator and tracheal tube for half an hour. This mode is an inverse ratio mode in which patient airway pressure is fluctuated between high pressure and low pressure. In this intervention, the duration of high pressure is 4.5 sec and duration of low pressure is 0.5 sec. he high-level pressure will be determined based on the patient's required tidal volume. All patients will receive synchronized intermittent mandatory ventilation (SIMV). Then the ventilation mode in patients in group 1 will be switched to APRV while in group II to SIMV and will be continue for another two hours. Afterwards, group 1 will receive SIMV and group II will receive APRV for two hours. In all three stages the values for ABG and vital signs (pao2, paco2, spo2, MAP, heart rate, blood pressure) will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080729234N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name

Fateme Soghra Farhangian

Name of organization / entity

Sabzevar University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Sabzevar University of Medical Sciences .

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Comparison of synchronized intermittent mandatory ventilation and airway pressure release

ventilation in oxynation and hemodynamic parameters in patients with head trauma.

Public title
Effect of mechanical ventilation on oxynation and hemodynamic in head trauma.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: age between 15 and 60 years; patients suffering from traumatic brain injuries who are intubated and are 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); Exclusion criteria: unstable hemodynamic (MAP <70); need to CPR.
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences.
Street address
Central beulding of Sabzevar University of Medical Sciences, Assadabadi street, Sabzevar.
City
Sabzevar
Postal code
9613873136
Approval date
2016-12-01, 1395/09/11
Ethics committee reference number
IR.MEDSAB.REC.1395.103

Health conditions studied

1

Description of health condition studied
Head trauma
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
Pressure of arterial oxygen
Timepoint
Before intervention, half an hour and 2 hours after intervention.
Method of measurement
Atrial blood gas (ABG).

2

Description
Pressure of arterial CO2
Timepoint
Before intervention, half an hour and 2 hours after intervention.
Method of measurement
Atrial blood gas (ABG)

3

Description
Aterial oxygen saturation
Timepoint
Before intervention, half an hour and 2 hours after intervention.
Method of measurement
Monitore

Secondary outcomes

1

Description
Mean artery pressure
Timepoint
Before intervention, half an hour and 2 hours after intervention.
Method of measurement
Sphygmomanometer

2

Description
Heart rate

Timepoint
Before intervention, half an hour and 2 hours after intervention.
Method of measurement
Number in minute

3

Description
Systolic pressure
Timepoint
Before intervention, half an hour and 2 hours after intervention.
Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention of this research is a ventilation mode is called Airway Pressure Release Ventilation that will be applied through ventilator and tracheal tube for half an hour. This mode is an inverse ratio mode in which patient airway pressure is fluctuated between high pressure and low pressure. In this intervention, the duration of high pressure is 4.5 sec and duration of low pressure is 0.5 sec. The high-level pressure will be determined based on the patient's required tidal volume. The patients in group 1 will receive SIMV for two hours then ABG will be taken half an hour and two hours after changes. Then ventilator mode will be switched to APRV for two hours and ABG will be taken half an hour and two hours later. In all stages the values for ABG and vital signs will be recorded.
Category
Other

2

Description
The patients in group 2 will receive APRV for two hours and after that ABG will be taken half an hour and two hours after changes. Then ventilator mode will be switched to SIMV for two hours and ABG will be taken half an hour and two hours later. In all stages the values for ABG and vital signs will be recorded.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Taleghani Hospita
Full name of responsible person
Dr Hassan Sadeghi
Street address
Taleghani Hospital, Ferdowsi three ways, Asiaeii highway, Masshhad.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Sabzevar University of Medical Sciences
Full name of responsible person
Akrami Rahim
Street address
Vice Chancellor for research of Sabzevar University of Medical Sciences, block B, University campus building, Tohidshahr boulevard, Sabzevar.
City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Sabzevar University of Medical Sciences
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
Sabzevar University of Medical Sciences
Full name of responsible person
Hassan Khalili
Position
MSc in nursing
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Person responsible for scientific inquiries

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Other areas of specialty/work

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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