

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Effectiveness Airway pressure release ventilation mode on hemodynamics and oxygenation intracranial pressure and cerebral trauma patients than routine fashion ventilation (Synchronized intermittent mandatory ventilation)

Protocol summary

Summary

The aim of this study is survey the effect of airway pressure release ventilation mode on intracranial pressure, oxygenation and hemodynamic of patients with traumatic brain injury. This study is a Triple-blind (patient, data collector and analyzer) randomized clinical trial with two-groups. 50 patients 18-70 years old with brain injuries and need ventilator, with GCS <9 and without COPD are divided into two groups. In control group at least one hour after SIMV / PSV mode, all intracranial pressure variables and hemodynamic and oxygenation parameters will be measured by the researcher. After an hour of ventilation in SIMV / PSV mode, again all variables will be measured at the same condition. In experimental group, at least one hour after SIMV / PSV mode, all the above variables, will be measured and then patient ventilate for an hour with APRV mode. At the end of an hour, then all mentioned variables will be measured at the same condition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021426558N1**

Registration date: **2016-06-10, 1395/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name

Maryam Safari Bidokhti

Name of organization / entity

Shahrood University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahrood University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness Airway pressure release ventilation mode on hemodynamics and oxygenation intracranial pressure and cerebral trauma patients than routine fashion ventilation (Synchronized intermittent mandatory ventilation)

Public title

The influence of some kind of ventilation on the heart and brain and lungs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 70 years; TBI patients who underwent intubation and mechanical ventilation mode SIMV / PSV (due to intervention of the kind of pressure that fashion should be a routine fashion is also a kind of pressure) are hemodynamic stability (MAP> 70 mm Hg and lasting at least 30 minutes before the start of the study); ALI according to the anesthesiologist and intensive care; GCS <9; lack of chronic obstructive pulmonary disease (COPD), according to the anesthesiologist and intensive care, having Vntryklvstvmy catheters for intracranial pressure monitoring, the patient is RASS of -3.

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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Medical Sciences shahrood

Street address

Shahrood- Hafte-Tir Square

City

Shahrood

Postal code

Approval date

2016-01-25, 1394/11/05

Ethics committee reference number

IR.SHMU.REC.1394.184

Health conditions studied

1

Description of health condition studied

head Trauma

ICD-10 code

S09

ICD-10 code description

Other and unspecified injuries of head

Primary outcomes

1

Description

Oxygenation

Timepoint

Baseline, one hour later

Method of measurement

Arterial blood samples

2

Description

Increased Intracranial Pressure

Timepoint

Baseline, one hour later

Method of measurement

ventriclostomy

3

Description

Hemodynamic

Timepoint

Baseline, one hour later

Method of measurement

Blood pressure measurement

Secondary outcomes

1

Description

blood pressure

Timepoint

Baseline, one hour later

Method of measurement

Blood pressure measurement

2

Description

intracranial pressure

Timepoint

Baseline, one hour later

Method of measurement

ventriclostomy

Intervention groups

1

Description

Use Airway pressure release ventilation (APRV) mode for an hour in the intervention group

Category

Treatment - Other

2

Description

Use Synchronized intermittent mandatory ventilation (SIMV) mode for an hour in the control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamyab Hospital

Full name of responsible person

Maryam Safari Bidokhti

Street address

Fadaeeian of Isalam Street

City

Mashhad

2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Maryam Safari Bidokhti

Street address

Sento Road

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Medical Sciences Shahrood

Full name of responsible person

Dr. Mohamad hasan Emamian

Street address

Shahrood, Hafte-Tir Square

City

Shahrood

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 and Technology of Medical Sciences Shahrood

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

Shahrood University of Medical Sciences

Full name of responsible person

Maryam Safari Beidokhti

Position

Nursing Graduate Student

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Web page address

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