Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of respiratory parameters in mechanical ventilation with Adaptive Support Ventilation (ASV) and Synchronized Intermittent Mandatory Ventilation (SIMV) in the hospitalized neurosurgical patients in ICU

Protocol summary

Summary

Objectives: The comparison of respiratory parameters in mechanical ventilation with Adaptive Support Ventilation (ASV) and Synchronized Intermittent Mandatory Ventilation (SIMV) in the hospitalized neurosurgical patients in ICU. Design: crossover randomized clinical trial, blocking randomization, single blind, Setting and conduct: one center (Firouzgar hospital, Tehran). Sample size: 54 patients. Interventions: for 30 minute 27 patients will be put on SIMV mode and 27 patients will be put on ASV mode, and then 2 groups will be relocated. Respiratory parameters will be measured at the first, during and at the end of each intervention. Major inclusion criteria: hospitalized in neurosurgery ICU; decreased consciousness; need to intubation and mechanical ventilation; no respiratory failure. Major exclusion criteria: severe liver failure; severe kidney failure; severe lung disease; confirmed obstructive lung diseases; confirmed restrictive lung diseases; heart failure; respiratory failure; involvement or lesion of brain stem. Main outcome measures: plateau pressure rate, peak flow rate, tidal volume, respiratory rate, arterial mean pressure, peripheral O2 saturation rate (SPO2)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112016151N3**
Registration date: **2015-11-28, 1394/09/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-28, 1394/09/07

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Iran University of Medical Siences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

a-pournajafian@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of respiratory parameters in mechanical ventilation with Adaptive Support Ventilation (ASV) and Synchronized Intermittent Mandatory Ventilation (SIMV) in the hospitalized neurosurgical patients in ICU

Public title

comparison of Adaptive Support Ventilation (ASV) and

Synchronized Intermittent Mandatory Ventilation (SIMV) modes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: hospitalized in neurosurgery ICU; decreased consciousness; need to intubation and mechanical ventilation; no respiratory failure. Exclusion criteria: severe liver failure (ascites, abnormal liver function tests); severe liver and renal failure ; severe lung disease based on PFT (FEV1<50%); confirmed obstructive lung diseases (asthma, emphysema, chronic bronchitis, small airway disease); bronchiectasis; confirmed restrictive lung diseases (fibrosis of lungs); heart failure (EF<45%); obesity (BMI>30); pregnancy; smoking; respiratory failure (MAP<60 mm/Hg, T>38, PH<7.3, PCO2>50, PO2<60 with FiO2<0.6); involvement or lesion of brain stem.

Age

To **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Randomization with blocking method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Iran University of Medical Sciences

Street address

hemmat highway, tehran

City

Tehran

Postal code

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

105/1678/93 /د

Health conditions studied

1

Description of health condition studied

mechanical ventilation

ICD-10 code

Z51.8

ICD-10 code description

Other specified medical care

Primary outcomes

1

Description

peak airway pressure

Timepoint

minutes 10,20,30

Method of measurement

cm H2O by ventilator

2

Description

static lung compliance

Timepoint

30 minutes after intervention

Method of measurement

ml/cm H20 by ventilator

3

Description

dynamic lung compliance

Timepoint

30 minutes after intervention

Method of measurement

ml/cm H20 by ventilator

Secondary outcomes

1

Description

arterial CO2

Timepoint

minutes 10,20,30

Method of measurement

mmHg by ABG

2

Description

arterial oxygen presuure

Timepoint

minutes 10,20,30

Method of measurement

mmHg by ABG

3

Description
respiratory rate
Timepoint
minutes 10,20,30
Method of measurement
rate in minute

Intervention groups

1

Description
Intervention group 1: sedation will be done for patients (with propofol 1-2 mg/kg/h) if they need. Patients will be given 1 mg midazolam (bolus) if they can't tolerate the tracheal tube (to be in Ramsy Score: 2-4). Analgesia level will be regulated for all patients with fentanyl based on VAS (0-3), between complete analgesia to mild pain. Patients will be put on SIMV mode for 30 min (FiO2:60%، TV: 8 cc/kg، PEEP: 3-5 cmH2O if arterial mean pressure>60 mmHg, ASB: 10 cmH2O, RR=12/min, ETCO2= 30-35, trigger: 3-5). Outcomes will be measured at 10, 20 and 30 min. Then patients will be put on ASV mode for 30 min and Outcomes will be measured again.
Category
Treatment - Devices

2

Description
Intervention group 2: sedation will be done for patients (with propofol 1-2 mg/kg/h) if they need. Patients will be given 1 mg midazolam (bolus) if they can't tolerate the tracheal tube (to be in Ramsy Score: 2-4). Analgesia level will be regulated for all patients with fentanyl based on VAS (0-3), between complete analgesia to mild pain. Patients will be put on ASV mode for 30 min (FiO2:60%، TV: 8 cc/kg، PEEP: 3-5 cmH2O if arterial mean pressure>60 mmHg, ASB: 10 cmH2O, RR=12/min, ETCO2= 30-35, trigger: 3-5). Outcomes will be measured at 10, 20 and 30 min. Then patients will be put on SIMV mode for 30 min and Outcomes will be measured again.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Dr Mohammad Hosein Hemadi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of research of Iran University of Medical Sciences
Full name of responsible person
Dr Mohammad Mousavi
Street address
Next to Milad tower, Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of research of Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr. Alireza Pournajafian
Position
Assisstant professor of anesthesia
Other areas of specialty/work
Street address
Firoozgar Hospital, Beh Afarin street, Karim Khan blvd.
City
Tehran
Postal code
Phone
+98 21 8894 6762
Fax
Email
alipn78@yahoo.com; pournajafian.ar@iums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Alireza Pournajafian

Position

Anesthesia Board

Other areas of specialty/work

Street address

Firoozgar Hospital, Beh Afarin street, Karim Khan blvd.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

alipn78@yahoo.com, pournajafian.ar@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University pf Medical Sciences, Anesthesia department

Full name of responsible person

Dr Mohammad Hosein Hemadi

Position

Resident of anesthesia

Other areas of specialty/work

Street address

City

Tehran

Postal code

Phone

00

Fax

Email

dr_hemadi@yahoo.com

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