Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of Adaptive Support Ventilation and Synchronized Intermittent Mandatory Ventilation in patients with ARDS: A randomized clinical trial

Protocol summary

Study aim

this study aims to assess the respiratory, arterial blood gas (ABG) and hemodynamic effects of the ASV mode compared to the SIMV mode in patients with ARDS in ICU.

Design

a parallel, randomized controlled trial, phase 3 randomization method: Block randomization. Sample size: 32. consist of two groups receiving intervention 1 and 2.

Settings and conduct

The protocol of this prospective randomized controlled trial is approved by the Ethics Committee of the Isfahan University of Medical Sciences. 32 eligible patients diagnosed with ARDS who are hospitalized in the ICU of AL-Zahra hospital, Isfahan are enrolled. Patients are allocated into two groups of intervention to receive intervention 1 (SIMV) and 2 (ASV). the mentioned outcomes are measured for 3 days. Lung protection strategies are continued for three days. Statistical analyses are done using SPSS version 23. Different tests are used as necessary and appropriate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-70 years old, expected duration of ventilation >72 hours, no acute renal failure, stable hemodynamic without vasopressor drugs, BMI < 30, acute hypoxemia (P/F ratio <300 mm Hg), and bilateral established infiltration based on chest radiograph. Exclusion criteria: chronic lung disease, pregnancy, smoking, heart failure (EF < 45%), the existence of any brainstem lesions, clinical evidence of left atrial hypertension, and apnea, death, withdrawal from the ICU before 72 hours, and having sepsis.

Intervention groups

intervention 1: people with ARDS who receive Adaptive Support Ventilation intervention 2: people with ARDS who receive Synchronized Intermittent Mandatory Ventilation.

Main outcome variables

Rapid shallow breathing index; Peak inspiratory pressure (cm H2O); Spontaneous breathing rate (breaths/min); Minute volume (L/min)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190908044730N1**
Registration date: **2019-12-11, 1398/09/20**
Registration timing: **retrospective**

Last update: **2019-12-11, 1398/09/20**
Update count: **0**

Registration date

2019-12-11, 1398/09/20

Registrant information

Name

Mojtaba Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3335 9933

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-01, 1396/03/11

Expected recruitment end date

2018-06-01, 1397/03/11

Actual recruitment start date
2017-06-01, 1396/03/11
Actual recruitment end date
2018-03-01, 1396/12/10
Trial completion date
2018-03-30, 1397/01/10

Scientific title
Comparison of Adaptive Support Ventilation and Synchronized Intermittent Mandatory Ventilation in patients with ARDS: A randomized clinical trial

Public title
Adaptive Support Ventilation and Synchronized Intermittent Mandatory Ventilation in patients with ARDS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
expected duration of ventilation more than 72 hours no acute renal failure stable hemodynamic without using drugs BMI < 30 acute hypoxemia (P/F ratio <300 mm Hg) bilateral infiltration based on chest radiograph.
Exclusion criteria:
chronic lung disease pregnancy smoking heart failure (EF < 45%) existence of any brainstem lesions clinical evidence of left atrial hypertension apnea
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **32**
Actual sample size reached: **16**
Randomization (investigator's opinion)
Randomized
Randomization description
Using stratified block randomization (stratification was based on disease severity: mild, moderate, severe), eligible patients were randomly allocated into two groups of intervention to receive mechanical ventilation with either SIMV or ASV mode. Random allocation was computerized using specialized Random allocation software.
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
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan Province, Isfahan, hezar jarib street, Isfahan University of Medical Sciences
City
Isfehan
Province
Isfehan
Postal code
81746 73461
Approval date
2017-08-23, 1396/06/01
Ethics committee reference number
پروپوزال این طرح در سال 96 تصویب شده است و پروپوزال های قبل از سال 1397 فاقد کد اخلاق ملی هستند. قابل ذکر است گه کمیته اخلاق داشگاه علوم پزشکی اصفهان در لیست کمیته اخلاق های مورد تایید وزارت بهداشت وجود دارد. کد طح تصویب شده: 39665 می باشد. کد اخلاق داخلی

Health conditions studied

1

Description of health condition studied
patients diagnosed with acute respiratory distress syndrome (ARDS)
ICD-10 code
J80
ICD-10 code description
Acute respiratory distress syndrome

Primary outcomes

1

Description
rapid shallow breathing index (RSBI)
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

2

Description
spontaneous breathing rate (SBR)
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

3

Description
minute volume

Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

4

Description
peak inspiratory pressure (PIP)
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

Secondary outcomes

1

Description
ABG parameters including; PaO2, FiO2, PaCO2, HCO3 and PaO2/FiO2 ratio
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

2

Description
mean arterial blood pressure (MABP)
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

3

Description
heart rate (HR)
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
medical ventilator

4

Description
PH level
Timepoint
at baseline and daily for 3 days after intervention
Method of measurement
Arterial blood gas test

Intervention groups

1

Description
Intervention group: Adaptive Support Ventilation
Category
Treatment - Devices

2

Description
Intervention group: Synchronized Intermittent Mandatory Ventilation
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
AL-Zahra hospital
Full name of responsible person
Babak Ali kiyaei
Street address
Soffe Boulevard, Isfahan, Iran
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Web page address
http://alzahra.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Research Deputy
Street address
Research Deputy, Building no. 4, Isfahan University of Medical Sciences, Hezar Jarib Street,
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamideh Yari
Position
-
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
there is no plan to make this available at the moment.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available