Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of the effect of using Adaptive support ventilation (ASV) in comparison with Synchronized intermittent mandatory ventilation (SIMV) method on lung mechanics in Respiratory Failure Patients Hospitalized in Intensive Care Unit

Protocol summary

Study aim
Evaluation of the effect of using Adaptive support ventilation (ASV) in comparison with Synchronized Intermittent Mandatory Ventilation (SIMV) method on lung mechanics (compliance, resistance) in Respiratory Failure patients admitted to intensive care unit

Design
A randomised clinical trial with a control group, with parallel, unblinded,randomized groups on 64 patients.A computer-generated random number table is used for randomization

Settings and conduct
In both groups, if the following conditions are present, patient is extubated: Rapid Shallow Breathing Index<105, pulmonary compliance above 40 mL/cmH20, resistance less than 10 cmH20/L/s, SBP more than 90mmHg

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients with acute type I respiratory failure with endotracheal intubation and mechanical ventilation for less than 48 hours are admitted based on P / F Ratio = 150-250 ؛Exclusion criteria:Patients with neuromuscular or diaphragmatic disorder,chest deformity,suspected intracranial hypertention,chronic obstructive pulmonary disease or severe asthma,chronic heart failure,chronic renal failure,refractory shock,diagnosed barotrauma,lungs contusion,under 16 years of age and over 85 years,pregnancy,abdominal compartment syndrome

Intervention groups
In the ASV or intervention group,Minute Volume:100% and pressure set on 30 CmH2O to reach O2Saturation: 88-92% and PEEP = 5 and flow trigger 1-3 l / min.In SIMV group, when the patient reaches PEEP <8 cmH2O and FiO2 <0.4 and 8 PS <cmH2O, they go to spontaneous ventilation mode with the same ventilator towards FiO2: 40%, PEEP = 3cmH2O, PS = 3 cmH2O and trigger: 2.In both age and sex groups, IBW and APACHEII Score at the time of hospitalization and lung mechanics and ventilator and oxygenation settings (P / F Ratio) and ABG indices are recorded on days 1, 2, 3 and 7

Main outcome variables
Lung mechanics:compliance, resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161106030735N2**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date
2020-12-02, 1399/09/12

Registrant information

Name
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Name of organization / entity
Tehran University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-20, 1399/08/30
Expected recruitment end date
2020-12-20, 1399/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of using Adaptive support ventilation (ASV) in comparison with Synchronized intermittent mandatory ventilation (SIMV) method on lung mechanics in Respiratory Failure Patients Hospitalized in Intensive Care Unit

Public title
The effect of ASV ventilation mode on respiratory failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Intubated patients with acute respiratory failure type I (hypoxemic) Endotracheal intubation and mechanical ventilation less than 48 hours Respiratory failure based on PaO2/FiO2=150-250 (P / F Ratio = 150-250)
Exclusion criteria:
Patients with acute respiratory failure and PaO2/FiO2(P / F Ratio) less than 150 Neuromuscular and diaphragmatic disorders Chest deformity Suspected Intracranial Hypertension Chronic obstructive pulmonary disease and severe asthma Chronic heart failure Chronic renal failure Refractory shock Diagnosed Barotrauma and Lung Contusion Age under 16 and over 85 years Pregnancy Abdominal compartment syndrome
Age
From **16 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The two groups are divided based on a list of random numbers generated by computer software.Based on the number list with numbers 1 for ASV and 2 for SIMV, patients are randomly divided and entered the study, respectively.
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
Ethic cmmittee,faculty of medicine of Tehran University of mdical science
Street address
Tehran universiy of medical science, faculty of medicine, Poorsina street,Keshavarz avenue
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Tehran
Postal code
1411713135
Approval date
2019-12-10, 1398/09/19
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.633

Health conditions studied

1

Description of health condition studied
Acute hypoxemic respiratory failure
ICD-10 code
J96.01
ICD-10 code description
Acute respiratory failure with hypoxia

Primary outcomes

1

Description
Lung compliance
Timepoint
Measurement of lung compliance on days 1, 2, 3 and 7 after ASV or SIMV setting
Method of measurement
compliance measurment is based on ventilator information

2

Description
Lung resistance
Timepoint
Measurement of lung resistance on days 1, 2, 3 and 7 after ASV or SIMV setting
Method of measurement
resistance measurment is based on ventilator information

Secondary outcomes

1

Description
Acute Physiologic Assessment and Chronic Health Evaluation (APACHE) II Scoring System
Timepoint
At the time of admission
Method of measurement
According to the case report

2

Description
Oxygenation based on the ratio of arterial oxygen pressure to the Fio2
Timepoint
Days 1, 2, 3 and 7 after the start of ventilation mode
Method of measurement
Based on sample information of ABG blood gas analysis

3

Description
Arterial blood carbon dioxide pressure PaCO2
Timepoint
Days 1, 2, 3 and 7 after the start of ventilation mode
Method of measurement
Based on sample information of ABG blood gas analysis

4

Description
Fentanyl intake
Timepoint
Days 1, 2, 3 and 7 after the start of ventilation mode
Method of measurement
Based on patient record (micrograms)

5

Description
number of ventilator free days at day 28
Timepoint
Twenty-eighth day after intervention
Method of measurement
Based on patient record

6

Description
Intensive care unit length of stay
Timepoint
At the time of discharge from the intensive care unit
Method of measurement
Based on patient record

7

Description
Richmond Agitation and Sedation Scale (RASS score)
Timepoint
Days 1, 2, 3 and 7 after the start of ventilation mode
Method of measurement
Based on patient record

Intervention groups

1

Description
In the ASV or intervention group,Minute Volume:100% and pressure set on 30 CmH2O to reach O2Saturation: 88-92% and PEEP = 5 and flow trigger 1-3 l / min.As the patient's condition improves, the minute volume is reduced to 70% and then to 50% and then 30% to reach a minimum pressure of 5 cmH2O
Category
Treatment - Devices

2

Description
Control group:In SIMV group, when the patient reaches PEEP <8 cmH2O and FiO2 <0.4 and 8 PS <cmH2O, they go to spontaneous ventilation mode with the same ventilator towards FiO2: 40%, PEEP = 3cmH2O, PS = 3 cmH2O and trigger: 2
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Elham Naseh

Position
ICU fellowship

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Individual data is recorded and archived in the datasheet. All data can be shared after unidentifiable study subjects.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
No other analysis is allowed.

From where data/document is obtainable
To receive the data, they can send a request to the following email address. enaseh@razi.tums.ac.ir

What processes are involved for a request to access data/document
To receive the data, they can send a request to the following email address. enaseh@razi.tums.ac.ir. Information will be made available to eligible individuals within 24 hours.

Comments