

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/cmH₂O, resistance less than 10 cmH₂O/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 hypertension, 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 O₂ Saturation: 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

Elham Naseh

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 84901

Email address

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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 committee, faculty of medicine of Tehran University of medical science

Street address

Tehran university of medical science, faculty of medicine, Poorsina street, Keshavarz avenue

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Tehran

Province

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 measurement 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 measurement 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 F_{iO_2}

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 P_{aCO_2}

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 cmH_2O to reach O_2 Saturation: 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 cmH_2O

Category

Treatment - Devices

2

Description

Control group: In SIMV group, when the patient reaches PEEP < 8 cmH_2O and F_{iO_2} < 0.4 and 8 PS < cmH_2O , they go to spontaneous ventilation mode with the same ventilator towards F_{iO_2} : 40%, PEEP = 3 cmH_2O , PS = 3 cmH_2O and trigger: 2

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhoondzadeh

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Web page address

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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Atabak Najafi

Position

Professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Elham Naseh

Position

ICU Fellowship

Latest degree

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Other areas of specialty/work

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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