

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of using Airway Pressure Release Ventilation (APRV) in comparison with Pressure Support Ventilation (PSV) method in lung mechanics in patients with Acute Respiratory Failure (ARF) admitted to intensive care unit

Protocol summary

Study aim

Evaluation of the effect of using APRV in comparison with PSV in lung mechanics in patients with respiratory failure admitted to intensive care unit

Design

A randomised clinical trial with a control group, with parallel, unblinded, randomized groups on 52 patients. A computer-generated random number table is used for randomization

Settings and conduct

In the APRV and PSV group, if the following conditions are present, patient is extubated: RSBI <105, pulmonary compliance above 40, resistance less than 10, SBP > 90

Participants/Inclusion and exclusion 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. Patients with neuromuscular or diaphragmatic disorder or chest deformity or suspected intracranial hypertension or chronic obstructive pulmonary disease or severe asthma or chronic heart failure or chronic renal failure or refractory shock or diagnosed barotrauma or lungs contusion or under 16 years of age and over 85 years, or pregnancy or abdominal compartment syndrome are excluded

Intervention groups

Intervention group: Patients switch from previous PSV ventilation mode to APRV mode. PaO₂ above 60. The T-low is set to 1 to 1.5 times the expiratory time constant (TE). T-high is adjusted so that the release frequency is set to 10-14 / min and PaCO₂ is kept in the normal range. Control group: Pressures are applied on the pressure mode with PIP and PS with the aim of creating a tidal volume equal to 6ml / kg of predicted body weight and PEEP is adjusted to the extent that with FIO₂ less than 60%, PaO₂ above 60. In both age and sex

groups, IBW and APACHE II 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: **IRCT20200509047376N1**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

arash najafi abranda badi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-12, 1399/08/22
Expected recruitment end date
2021-01-04, 1399/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of using Airway Pressure Release Ventilation (APRV) in comparison with Pressure Support Ventilation (PSV) method in lung mechanics in patients with Acute Respiratory Failure (ARF) admitted to intensive care unit

Public title
The effect of APRV 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 P / F Ratio = 150-250
Exclusion criteria:
Patients with acute respiratory failure and P / F Ratio less than 150 Neuromuscular and diaphragmatic disorders Chest deformity Suspected Intracranial Hypertension COPD and severe asthma CHF CKD , ESRD 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: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
The two groups are divided based on random numbers generated by computer software.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Sina Hospital, Imam Khomeini Ave., Imam Khomeini Square
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2019-02-23, 1397/12/04
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.848

Health conditions studied

1

Description of health condition studied
Acute hypoxemic respiratory failure
ICD-10 code
J96.0
ICD-10 code description
Acute respiratory failure

Primary outcomes

1

Description
Lung compliance. Lung resistance
Timepoint
Measurement of lung compliance and resistance on days 1, 2, 3 and 7 after long-term onset of APRV and PSV
Method of measurement
compliance and 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 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

روزهای 1 و 2 و 3 و 7 بعد از شروع مد تهویه ای

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

8

Description

The amount of shunt: $(1-SaO_2)/(1-SvO_2)$

Timepoint

Days 1, 2, 3 and 7 after the start of ventilation mode

Method of measurement

Based on ABG information

Intervention groups

1

Description

Intervention group: APRV: Patients change from previous volume ventilation mode to APRV mode. P-high is adjusted to create VT = 6ml / kg and does not exceed 30cmH₂O. From 60%, produce PaO₂ above 60. The T-low is set to 1 to 1.5 times the expiratory time constant (TE). T-high is adjusted so that the release frequency is set to 10-14 / min and PaCO₂ is maintained in the normal range.

Category

Treatment - Devices

2

Description

Control group: PSV: Patients on pressure mode with PIP and PS with the aim of creating a tidal volume equal to 6 ml per kg of ideal weight. PEEP to the extent that with FIO₂ less than 60%, PaO₂ above 60 Slowly adjusted.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Arash Najafi Abrand Abadi

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Imam Khomeini Ave.

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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

Street address

Faculty of Medicine, Tehran University of Medical sciences, Poorsina street, Keshavarz avenue

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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**Contact****Name of organization / entity**

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Atabak Najafi

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**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

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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

En To receive the data, they can send a request to the following email address. elhamnaseh63@gmail.com

What processes are involved for a request to access data/document

En To receive the data, they can send a request to the following email address. elhamnaseh63@gmail.com. Information will be made available to eligible individuals within 24 hours.

Comments