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 than10, 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 hypertention 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 APACHEII Score at the time of hospitalization and lung mechanics and ventilator and oxygenation settings(P / F Ratio) and ABG indices are recorded on days1, 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 abrandabadi

Name of organization / entity

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Iran (Islamic Republic of)

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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 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
روزهای 1و2و3و7 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-SaO2)/(1-SvO2)
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
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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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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
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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
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