

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of APRV-LTV mechanical ventilation mode on arterial blood gases, ventilation indices and vital signs in patients with COVID-19

Protocol summary

Study aim

The effect of APRV-LTV mechanical ventilation mode on arterial blood gases, ventilation indices and vital signs in patients with COVID-19

Design

Randomized clinical trial, with a control group, parallel groups. The sample size is 70 patients that randomly will be assigned to control and intervention groups using the block randomization method.

Settings and conduct

This study will be performed in the critical care units of Shahid Beheshti Hospital in Qom. No blinding will be performed in this study. Patients in the control group will be ventilated using SIMV mechanical ventilation mode. Patients in the intervention group will be ventilated using APRV-LTV mechanical ventilation mode. Patients' respiratory indicators and vital signs will be measured in the stages of immediately before and 2 and 4 hours after starting the ventilation.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: age over 18 years; having informed consent to participate in the study.

Intervention groups

Patients in the intervention group will be ventilated using APRV-LTV mechanical ventilation mode. Patients in the control group will be ventilated using SIMV mechanical ventilation mode.

Main outcome variables

Stabilization of vital signs and respiratory indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150724023314N4**

Registration date: **2021-09-04, 1400/06/13**

Registration timing: **prospective**

Last update: **2021-09-04, 1400/06/13**

Update count: **0**

Registration date

2021-09-04, 1400/06/13

Registrant information

Name

Mohammad Abbasinia

Name of organization / entity

Qom university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of APRV-LTV mechanical ventilation mode on arterial blood gases, ventilation indices and vital signs in patients with COVID-19

Public title

The effect of APRV-LTV mechanical ventilation mode in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years No history of chronic respiratory diseases such as COPD Having a endotracheal tube and being connected to mechanical ventilation

Exclusion criteria:

The patient refuses to participating in the study
Instability of the patient's vital signs

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to intervention and control groups using block randomized method. The link "<https://www.sealedenvelope.com/simple-randomiser/v1/lists>" will be used for block randomization. For this purpose, the target number of samples (100 samples including sample loss), number of groups (two groups A and B) and number of blocks (4) will be entered and the system will provide the researcher with a list of 4 blocks. Based on the output list, it will be determined in which group the patients who enter the study should be placed in order. Items A represent the intervention group and items B represent the control group.

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 Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Saheli street, Qom

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

IR.MUQ.REC.1400.065

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Blood pressure

Timepoint

Immediately before, 2 and 4 hours after the start of ventilation

Method of measurement

Vital Sign Monitoring Device

2

Description

Heart rate

Timepoint

Immediately before, 2 and 4 hours after the start of ventilation

Method of measurement

Vital Sign Monitoring Device

3

Description

Respiratory rate

Timepoint

Immediately before, 2 and 4 hours after the start of ventilation

Method of measurement

Vital Sign Monitoring Device

4

Description

Static compliance rate

Timepoint

Immediately before, 2 and 4 hours after the start of ventilation

Method of measurement

Vital Sign Monitoring Device

5

Description

PaO₂ / FiO₂ ratio

Timepoint

Immediately before, 2 and 4 hours after the start of ventilation

Method of measurement

Vital Sign Monitoring Device

6

Description

Arterial blood oxygen saturation

Timepoint

Immediately before, 2 and 4 hours after the start of ventilation

Method of measurement

Vital Sign Monitoring Device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: from 24 hours after the start of mechanical ventilation for 7 days, every morning, patients were ventilated for 4 hours in APRV-LTV mode.

Category

Other

2

Description

Control group: from 24 hours after the start of mechanical ventilation for 7 days, every morning, patients were ventilated for 4 hours in SIMV mode.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Qom

Full name of responsible person

Mohammad Abbasinia

Street address

Shahid Beheshti Hospital, Shahid Beheshti Boulevard, Qom

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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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Mohammad Abbasinis

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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