

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effects of two modalities of adaptive support ventilation and pressure-related volume control in terms of changes in heart rate and blood pressure and duration of separation from mechanical ventilation in patients admitted to the intensive care unit

Protocol summary

Study aim

Evaluation of the effects of two modalities of adaptive support ventilation and pressure-related volume control in terms of changes in heart rate and blood pressure and duration of separation from mechanical ventilation in patients admitted to the intensive care unit

Design

Clinical trial with control group with parallel, randomized groups, phase 3 on 74 patients. The random number table was used for randomization

Settings and conduct

This study is performed in Al-Zahra Hospital in Isfahan. Patients are randomly divided into two groups. The first group is treated with adaptive support ventilation modality by the ventilator and the second group is even treated with pressure-related volume control modality by the ventilator. Patients will be examined by physicians for changes in heart rate, blood pressure, and duration of separation from the mechanical ventilator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 18-70 years old admitted to the intensive care unit, requiring mechanical ventilation, ability to perform both modalities for patients and having informed consent of co-patients to participate in the study. Exclusion criteria: Chronic lung disease prior to study, multiple organ failure at admission

Intervention groups

Intervention group: Patients in this group are treated with adaptive support ventilation modality by a ventilator. Patients will be examined by physicians for changes in heart rate, blood pressure, and duration of separation from the mechanical ventilator. Control group: Patients in this group are treated with pressure-related volume control modality by a ventilator. Patients will be examined by physicians for changes in heart rate, blood pressure, and duration of separation from the

mechanical ventilator.

Main outcome variables

Heart rate changes, Blood pressure changes, Duration of separation from the mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022681N3**

Registration date: **2020-08-06, 1399/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 195 1374

Email address

alikiaib@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-25, 1399/05/04

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of two modalities of adaptive support ventilation and pressure-related volume control in terms of changes in heart rate and blood pressure and duration of separation from mechanical ventilation in patients admitted to the intensive care unit

Public title

Effects of two modalities of adaptive support ventilation and pressure-related volume control in terms of changes in heart rate and blood pressure and duration of separation from mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalization in the intensive care unit
Requiring mechanical ventilation
Age 18 to 70 years
Ability to perform both modalities for patients
Having informed consent of co-patients to participate in the study

Exclusion criteria:

Previous Chronic lung disease
Multi-organ failure at admission

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **74****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group. The researcher begins to read the numbers in a predetermined manner and the patients are divided.

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 Esfahan university of Medical sciences

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

813786615

Approval date

2019-06-17, 1398/03/27

Ethics committee reference number

IR.MUI.MED.REC.1398.155

Health conditions studied**1****Description of health condition studied**

Hospitalized in the intensive care unit and requiring mechanical ventilation

ICD-10 code

R06.81

ICD-10 code description

Apnea, not elsewhere classified

Primary outcomes**1****Description**

Heart rate changes

Timepoint

Every hour until the first 6 hours and then from 6 hours to 24 hours and then daily

Method of measurement

By ECG

2**Description**

Blood pressure changes

Timepoint

Every hour until the first 6 hours and then from 6 hours to 24 hours and then daily

Method of measurement

By sphygmomanometer

3**Description**

Duration of separation from the mechanical ventilation

Timepoint

Every hour until the first 6 hours and then from 6 hours to 24 hours and then daily

Method of measurement

By checklist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in this group are treated with adaptive support ventilation modality by a ventilator. Patients will be examined by physicians for changes in heart rate, blood pressure, and duration of separation from the mechanical ventilator.

Category

Treatment - Devices

2**Description**

Control group: Patients in this group are treated with pressure-related volume control modality by a ventilator. Patients will be examined by physicians for changes in heart rate, blood pressure, and duration of separation from the mechanical ventilator.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra hospital

Full name of responsible person

Babak Alikiaii

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

alikiaib@med.mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

haghjoo.sh@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Babak Alikiaii

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3337 7986

Email

alikiaib@med.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences
Full name of responsible person
Babak Alikiaii
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8137866515
Phone
+98 31 3337 7986
Email
alikiaii@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Babak Alikiaii
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan

Postal code
8137866515
Phone
+98 31 3337 7986
Email
alikiaii@med.mui.ac.ir

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments