

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating The Effect of Adjustment of Peep and Fio2 Based on Arterial Blood Oxygen Pressure on the Care and Treatment Outcomes of Icu Patients

Protocol summary

Study aim

Determining the effect of fio2 and peep adjustment based on arterial blood oxygen pressure on care and treatment outcomes of intensive care unit patients

Design

Clinical trial with control group, block random allocation, pilot study with 30 samples with SPSS software

Settings and conduct

The number of eligible patients in the intensive care unit of Imam Khomeini Hospital in Ahvaz is numbered and each 6 are divided into a block, for example, the first block of all intervention groups, 3 cases of hyperoxemia and 3 cases of hypoxemia. Arterial blood gas sample was recorded before the intervention and with the beginning of the intervention, the peep and fio2 parameters were changed under the supervision of an anesthesiologist for 7 days and every day a blood sample was recorded and placed in the sofa table.

Participants/Inclusion and exclusion criteria

Age group 60-18 years Intubation and connection to the ventilator GCS score of at least 6 No lung disease, lung cancer and Copd No entry: Use of muscle relaxants Post CPR patients Unstable hemodynamics

Intervention groups

15 people in the intervention group, 7 of whom have hypoxemia pao2 <60mmhg and 8 people have hyperoxemia Pao2> 120mmhg, which are randomly divided into 6 blocks. In these two groups in the intervention group, due to arterial blood oxygen pressure, the two parameters of peep and fio2 decrease or increase during 7 days. And according to the sofa criterion, the patient's condition is evaluated. In the control group, 15 patients, including 7 patients with hypoxemia and 8 cases of hyperoxemia, and the parameters of peep and fio2 are routinely adjusted, and the sofa criterion is recorded within 7 days and the patient's condition is checked.

Main outcome variables

Effect on ventilator connection time, Effect on complications due to changes in arterial blood oxygen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200815048408N1**

Registration date: **2020-08-30, 1399/06/09**

Registration timing: **prospective**

Last update: **2020-08-30, 1399/06/09**

Update count: **0**

Registration date

2020-08-30, 1399/06/09

Registrant information

Name

Malihe Moghaddas ghahfarokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5352 3262

Email address

mgh.gh1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The Effect of Adjustment of Peep and Fio2 Based on Arterial Blood Oxygen Pressure on the Care and Treatment Outcomes of Icu Patients

Public title

"The effect of peep and fio2 modulation on outcome"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age group 60-18 years Intubation and connection to the ventilator GCS score of at least 6 No lung disease, lung cancer and COPD

Exclusion criteria:

Discharge or death of the patient before the intended time for intervention Use of muscle relaxants Post CPR patients Unstable hemodynamics

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random allocation method (5 blocks, each block including 6 patients are selected from both intervention and control groups. The number of possible cases from the arrangement of control and intervention patients is determined by MCMCMC that are not duplicates and 6 cases are randomly selected and to each Block is assigned a state, the first block of patients with hyperoxemia, the second block of patients with hypoxemia and also up to block 4 and the last block four to two of each group is placed in the control and intervention group of 8 patients with hyperoxemia and 7 patients with hypoxemia.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The study is a pilot and the sample size can be changed.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahwaz University of Medical Sciences

Street address

No. 368, Corner of Bustan 2., Bustan Street

City

Khoramshahr

Province

Khouzestan

Postal code

۶۴۱۷۷۱۷۷۴۳

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

lr.ajums.rec.1398.713

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

Changing the two parameters of peep and fio2 from the ventilator device according to the arterial blood oxygen pressure in the form of hypoxemia and hyperoxemia on the therapeutic outcomes and care of patients admitted to the intensive care unit.

ICD-10 code

T88.8

ICD-10 code description

Other specified complications of surgical and medical care, not elsewhere classified

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

Arterial blood oxygen pressure in the form of hypoxemia (Pao2<60mmhg)and hyperoxemia(Pao2>120mmhg).

Timepoint

Before the intervention and during 7 days of intervention

Method of measurement

arterial blood gases

Secondary outcomes

empty

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

Intervention group: 15 people in the intervention group, 7 of whom have hypoxemia pao2 <60mmhg and 8 people have hyperoxemia Pao2> 120mmhg, which are randomly divided into 6 blocks.In these two groups in the

intervention group, due to arterial blood oxygen pressure, the two parameters of peep and fio2 decrease or increase during 7 days. And according to the sofa criterion, the patient's condition is evaluated.

Category

Treatment - Devices

2**Description**

Control group: 15 patients, including 7 patients with hypoxemia and 8 cases of hyperoxemia, and the parameters of peep and fio2 are routinely adjusted, and the sofa criterion is recorded within 7 days and the patient's condition is checked.

Category

Treatment - Devices

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

Imam Khomeini Hospital

Full name of responsible person

Malihe Moghaddas Ghahfarokhi

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Email

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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad badavi

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Malihe Moghaddas Ghahfarokhi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Reports on blood test, sex, age, date of hospitalization, length of hospital stay, underlying disease, ventilator parameters

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

Employees in universities and researchers

Under which criteria data/document could be used

Help improve the condition of patients admitted to the intensive care unit, help reduce costs, use as a resource for other research.

From where data/document is obtainable

Email address

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

Have basic scientific information about ventilators

Comments