Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

the effect of ventilator settings based on diaphragm thickening fraction on diaphragm atrophy

Protocol summary

Study aim
In this study, we are investigating the effect of ventilator settings based on diaphragm thickness fraction on diaphragm atrophy.

Design
A parallel, double-blind, randomized controlled clinical trial on 40 critically ill poisoning patients admitted to the intensive care unit. The random sequence will be generated through randomization.com. Randomization will be done in blocks of 4

Settings and conduct
This study is carried out in ICUs of Imam Reza (AS) hospital. On 40 critically ill patients hospitalized in ICU who were intubated in the last 24 hours, in this study, in the intervention group, the ventilator was set to PCV mode. Settings are based on DTF. If the DTF is above 30%, the inspiratory pressure increases and if it is less than 15%, the inspiratory pressure decreases. The control group uses the usual ventilator settings. The researcher and the outcome evaluator do not know the group in which the patients are located. And the analyst does not know the group in which the patients are located.

Participants/Inclusion and exclusion criteria
Intubated patients: 1. Over 18 years old 2. Having informed consent (from the family) 3. Intubated in the last 24 hours. and be on PCV mode of ventilator 4. Absence of these diseases: lung disease, myopathy, brain disease, connective tissue disease 5. Absence of poisoning with things that cause muscle paralysis.

Intervention groups
Intervention group: In the normal settings of the ventilator on PCVmode, the ventilator is set based on DTF. In this study, in the intervention group, diaphragm ultrasonography is performed every day and DTF is calculated, if the DTF is above 30%, in the same interval, the tidal volume is created at 6 to 8 cc/kg; Increased inspiratory pressure and if the DTF is less than 15%, in the same range; Inspiratory pressure decreases.

Main outcome variables
Diaphragm Atrophy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190510043545N3**
Registration date: **2023-11-06, 1402/08/15**
Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**
Update count: **0**
Registration date
2023-11-06, 1402/08/15

Registrant information
Name
seyed javad purafzali firuzabadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3728 2267
Email address
sjvdpurafzali@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-21, 1402/08/30
Expected recruitment end date
2024-03-20, 1403/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the effect of ventilator settings based on diaphragm thickening fraction on diaphragm atrophy

Public title
the effect of ventilator settings on diaphragm atrophy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Over 18 years with informed consent (from family) The patient has been intubated in the last 24 hours. be on (pressure controlled ventilator mode).

Exclusion criteria:
Absence of underlying diseases (like: lung disease, myopathy, brain disease, connective tissue disease) No poisoning with things that cause muscle paralysis.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The Random allocation rule is the simplest method of limited randomization. This method represents a large block for the entire sample size, which means that the balance in the number of people allocated to each group will be achieved at the end of the study. For this purpose, the researchers first determined a total sample size (40 people) and then randomly assigned groups of them to group A and the rest to group B. For example, in a study with a sample size of 40 people, 20 balls for the intervention group A and 20 balls for the control group B are placed in a lottery container, and then the balls are randomly removed from the container without replacement and the created sequence is recorded. It should be noted that random sequence generation will be done through randomization.com Allocation Concealment: Sealed envelopes Randomization Unit: Individual

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the researcher and the outcome evaluator do not know the group in which the patients are located. In this study, the data analyst does not know the group in which the patients are located.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Imam Reza hospital-Imam Reza Square, Ibn-e Sina Avenue, Mashhad - Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2023-02-28, 1401/12/09

Ethics committee reference number
IR.MUMS.IRH.REC.1401.082

Health conditions studied

1

Description of health condition studied
Diaphragm atrophy

ICD-10 code
J95.850

ICD-10 code description
Mechanical complication of respirator

Primary outcomes

1

Description
Diaphragm Thickness

Timepoint
daily for 3 days

Method of measurement
Ultrasonography

Secondary outcomes

1

Description
Diaphragm thickening fraction

Timepoint
Daily for 3 days

Method of measurement

Ultrasonography

Intervention groups

1

Description
Intervention group: In the normal settings of the ventilator on pcv (pressure control ventilation) mode, the ventilator is set based on DTF. If the DTF (diaphragm thickening fraction) is above 30%, the inspiratory pressure increases, and if it is less than 15%, the inspiratory pressure decreases. In this study, in the intervention group, diaphragm ultrasonography is performed every day and DTF is calculated, if the DTF is above 30%, in the same interval, the tidal volume is created at 6 to 8 cc/kg; Increased inspiratory pressure (settings tend to 8 cc/kg) and if the DTF is less than 15%, in the same range; Inspiratory pressure decreases. (settings tend to 6 cc/kg)

Category
Prevention

2

Description
Control group: The control group uses the usual settings of the ventilator. In the usual settings of the ventilator in the PCV mode (pressure control ventilation) , the inspiratory pressure is set so that the patient has a tidal volume between 6 and 8 ml/kg. And the peak inspiratory pressure should not increase from 30 h2o cm.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Seyed javad purafzali firuzabadi
Street address
Imam Reza hospital-Imam Reza Square, Ibn-e Sina Avenue, Mashhad - Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Javad Purafzali Firuzabadi
Position
Intensive care fellowship
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
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
Information about the outcomes of the study is published in a research paper
When the data will become available and for how long
At the same time as the article is published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Analysis for review articles and meta-analysis
From where data/document is obtainable
Correspond to this email: sjvdpurafzali@yahoo.com
What processes are involved for a request to access data/document
These items should be clearly explained in the requested email: - How to use information - The details of the research that wants to use this information. - Detailed information of the applicant After reviewing these items, an answer will be given immediately
Comments