Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of two Pressure and Volume control ventilation during one lung ventilation in thoracic surgeries on the gas exchanges and the respiratory mechanical variables

Protocol summary

Study aim

Comparision of the effect of two Pressure and Volume control ventilation during one lung ventilation in thorasic surgeries

Design

This study is a one-sided blind clinical trial, with parallel, randomized groups on 60 patients. For randomization, we use the block randomization method.

Settings and conduct

In both groups, after induction of anesthesia, the patient is intubated with a left round double lumen endotracheal tube. Then we take an arterial line from the radial artery. With the start of surgery, one-lung ventilation begins for patients with the following characteristics. In the pressure control ventilation group, mechanical ventilation begins with an airway pressure of 20 cm of water, a rate of respiration of 12 per minute. Gradual changes in airway pressure are used to achieve an ideal tidal volume of 6 ml / kg. In the volume control ventilation group, a tidal volume of 6 ml / kg and a respiration rate of 12 beats per minute are used to ventilate the patient. In both groups, we use a change in respiration rate to achieve adequate minute ventilation. Finally, the variables are measured and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA physical class < or = class III Patients with a body mass index between 20 and 35, Have grade 1 and 2 Mallampati on airway examination Exclusion criteria: Severe hypoxemia

Intervention groups

Intervention group: Patients who are candidates for chest surgery, after anesthesia, their ventilation is performed with ventilator pressure control mode. Control group: Patients who are candidates for chest surgery, after anesthesia, their ventilation is performed with ventilator volume control mode.

Main outcome variables

Arterial blood oxygen pressure, peak airway pressure, dynamic lung compliance, end-tidal Co2, respiratory dead space

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121107011398N15**
Registration date: **2022-01-03, 1400/10/13**
Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**
Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Mohammad Reza Ghodraty

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

m-ghodrati@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-07-11, 1401/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two Pressure and Volume control ventilation during one lung ventilation in thoracic surgeries on the gas exchanges and the respiratory mechanical variables

Public title

Comparison of pressure versus volume control ventilation in one lung ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidates for thoracic surgery under one-lung ventilation ASA physical class < or = class III Patients with a body mass index between 20 - 35

Exclusion criteria:

Severe preoperative hypoxemia (SPo2 lower than 88% with room air) Patient dissatisfaction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a randomized clinical trial in which patients are assigned to one of two study groups using simple randomization methods in order of their entry. The randomization unit is personal and using a lottery drawing method, the third person draws blindly a sealed paper on which one of two groups' name is written. Thus we could achieve a concealed random sequence for allocation of patients as the process of lottery is repeated for each new patient entered.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to this fact that the study is performed under general anesthesia, the participating patients do not know the group and type of intervention. There is no possibility for blinding the person who intervenes and records the outcomes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway next to Milad Tower, Tehran

City

Tehran

Province

Tehran

Postal code

8874113911

Approval date

2021-07-04, 1400/04/13

Ethics committee reference number

IR.IUMS.FMD.REC.1400.249

Health conditions studied

1

Description of health condition studied

Thoracic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Arterial blood oxygen pressure (PaO2)

Timepoint

Before starting one-lung ventilation and for second time, 30 min after start of one-lung ventilation

Method of measurement

Arterial blood gas analysis

2

Description

Peak airway pressure

Timepoint

After tracheal intubation and then every 15 min during one-lung ventilation

Method of measurement

By airway pressure monitoring device included in anesthesia machine

3

Description

End-tidal pressure of CO2

Timepoint
Every 15 min during surgery
Method of measurement
By Capnograph monitoring

Secondary outcomes

1

Description
Dynamic compliance of respiratory system
Timepoint
After tracheal intubation and then every 15 min during one-lung ventilation
Method of measurement
Using the standard formula and tidal volume divided in airway pressure

2

Description
Respiratory dead space
Timepoint
After tracheal intubation and then 30 min after one-lung ventilation starting
Method of measurement
Calculation by the use of arterial and end tidal PCo2 pressure

Intervention groups

1

Description
Intervention group: In the intervention group after induction of anesthesia and tracheal intubation with a left double lumen endotracheal tube, with the start of surgery, one-lung pressure control ventilation will begin for patients with the following characteristics: airway pressure = 20 cmH2O, respiratory rate = 12/min, to achieve the ideal tidal volume of 6 ml/kg gradual changes in airway pressure will be used. To achieve proper minute ventilation and maintain end-tidal carbon dioxide (ET-Co2) pressure in the range of 35-40 mmhg, the respiratory rate will be changed. For mechanical ventilation of patients the anesthesia machine model EDP-Neptune MEDEC made in Belgium is used.
Category
Treatment - Other

2

Description
Control group: In the control group, after induction of anesthesia, the patient was intubated with a left double lumen endotracheal tube. At the beginning of the surgery, one-lung volume control ventilation is started for patients with the following characteristics: tidal volume of 6 ml/kg and a respiratory rate of 12 per minute. A change in respiration rate will be used to achieve proper minute ventilation and maintain expiratory carbon dioxide pressure in the range of 35-40 mmhg. For mechanical ventilation of patients, the anesthesia machine model EDP-Neptune MEDEC made in Belgium is used.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Mohammad Reza Ghodraty
Street address
Anesthesia Department, Firoozgar Hospital, Behafarin St. Karim Khan Av.
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8894 6762
Email
ghodrati.mr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hosein Keyvani
Street address
Vice-Chancellor for Research and Technology, Iran University of Medical Sciences, Shahid Hemmat highway.
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8670 5501
Email
keyvani@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodraty

Position

Professor of Anesthesiology & Critical Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesia Department, Firoozgar Hospital, Behafarin St. Karim Khan Av.

City

Tehran

Province

Tehran

Postal code

8874113911

Phone

+98 21 8894 6762

Email

ghodrati.mr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodraty

Position

Professor of Anesthesiology & Critical Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesia Department, Firoozgar Hospital, Behafarin St. Karim Khan Av.

City

Tehran

Province

Tehran

Postal code

8874113911

Phone

+98 21 8894 6762

Email

ghodrati.mr@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodraty

Position

Professor of Anesthesiology & Critical Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesia Department, Firoozgar Hospital, Behafarin St. Karim Khan Av.

City

Tehran

Province

Tehran

Postal code

8874113911

Phone

+98 21 8894 6762

Email

ghodrati.mr@iums.ac.ir

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