Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

The comparison of two volume and pressure control ventilation modes on the gas exchange and mechanical parameters of respiratory system during laparoscopic bariatric surgeries, a cross over clinical trial.

Protocol summary

Study aim

Comparison of the effect of two ventilation methods with volume and pressure control on gas exchanges and mechanical variables of the respiratory system during obesity surgery.

Design

A randomized crossover single blind clinical trial, which 26 patients are divided randomly in two groups of 13. The study is in phase 3 trial and simple random allocation (lottery) is used for randomization.

Settings and conduct

This study is doing in Firoozgar teaching hospital. After induction of general anesthesia, in the first group, patients primarily will be put under volume control ventilation mode, which continue until 15 minutes after start of surgery and gas insufflation into the abdominal cavity, then ventilation changes to pressure control mode until the end of the operation. In second group ventilation start with pressure mode and then will be changed to volume mode same as the above mentioned manner. Patients and person who analyzing data will be blinded into intervention used in each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with body mass index between 40 and 55; Age over 18 years. Exclusion criteria: Patient dissatisfaction; History of severe respiratory diseases; History of advanced cardiovascular diseases.

Intervention groups

In the first group after induction of anesthesia, pulmonary ventilation begins with volume mode and continues until 15 minutes after gas is blown into the abdomen, then the mode of ventilation will be changed to pressure control mode til the end of surgery. In second group in opposite to the first group, primarily from pressure mode ventilation and then volume mode will be used as above mentioned arrangement.

Main outcome variables

O2saturation; Peak airway pressure; Arterial blood gas analysis; End tidal PCo2; Pulmonary dead space volume; Dynamic pulmonary compliance; Alveolar to arterial O2 pressure gradient.

General information

Reason for update

Record the realized time of the beginning of the patient recruitment and insert the time of the end of the trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121107011398N14**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-19, 1400/09/28**
Update count: **1**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Mohammad Reza Ghodraty

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date
2020-09-19, 1399/06/29
Actual recruitment start date
2020-04-29, 1399/02/10
Actual recruitment end date
2020-12-20, 1399/09/30
Trial completion date
2020-12-20, 1399/09/30

Scientific title
The comparison of two volume and pressure control ventilation modes on the gas exchange and mechanical parameters of respiratory system during laparoscopic bariatric surgeries, a cross over clinical trial.

Public title
Comparison of two volume and pressure control ventilation modes during laparoscopic bariatric surgeries.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obese patients candidated for bariatric surgeries with body mass index (BMI) 40-55 Patients older than 18 and lower than 60 years ASA physical class < or = class III
Exclusion criteria:
Patient dissatisfaction History of sever respiratory disease History of advanced cardiovascular disease
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **26**
Actual sample size reached: **40**
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' names 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 the fact that the general anesthesia study is performed, the participating patients do not know the group and type of intervention. There is no possibility of blinding the person who intervenes and records the outcomes.
Placebo
Not used
Assignment
Crossover
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, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1433933111
Approval date
2019-06-22, 1398/04/01
Ethics committee reference number
IR.IUMS.FMD.REC.1398.150

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
O2 saturation (SPo2)
Timepoint
Every 5 min during surgery
Method of measurement
With Pulse Oximeter

2

Description
End-tidal Co2
Timepoint
Every 5 min during surgery
Method of measurement
With Capnograph

3

Description
Peak airway pressure
Timepoint
Every 5 min during surgery
Method of measurement
By the monitor of anesthesia machine

4

Description
Arterial blood gas analysis
Timepoint
In 15 and 30 minutes after insufflation of gas into abdominal cavity.
Method of measurement
By sending arterial blood sample to laboratory.

Secondary outcomes

1

Description
Exhaled tidal volume
Timepoint
During Surgery
Method of measurement
By anesthesia machine

2

Description
Dynamic pulmonary compliance
Timepoint
Every 5 min during surgery
Method of measurement
Calculation of variable by using the amounts of airway pressure and tidal volume

3

Description
Respiratory dead space
Timepoint
Every 5 min during surgery
Method of measurement
Calculation by the use of arterial and end tidal PCo2 pressure

Intervention groups

1

Description
The study protocol being a crossover, each participating patient will receive both types of interventions. The main intervention in the study is the pressure controlled mode of mechanical ventilation during bariatric surgery and its comparison with standard (volume controlled) ventilation. For this purpose, the participating patients were randomly divided into to groups: in the first group and after the induction of anesthesia, the patients were subjected to volume controlled mode and by 15 minutes after the commencement of the surgery, and intra-abdominal CO2 insufflation, the pressure controlled mode is applied. [volume control and then pressure control (VC-PC)]. For the pressure controlled mode, the ventilator is adjusted as follows: airway pressure 20 cmH2O, respiratory rate of 12 per minute. The airway pressure is progressively increased to reach the ideal tidal volume (6-8 cc/kg of ideal body weight). On the other hand, for the volume-controlled mode, the ventilator is adjusted on 7 cc/kg of ideal body weight. For both methods, the respiration rate module is used to keep the end tidal CO2 rate at 35-40 mmHg.
Category
Treatment - Other

2

Description
Control group: In second group the selection of ventilation mode is in opposite to the first group [Pressure control - Volume Control (PC-VC)]. The EDP-Neptune MEDEC BENELUX NV (BELGIUM) anesthesia machine and its ventilator were used for ventilation during anesthesia for both ventilation modes
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Mohammad Reza Ghodraty
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran 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
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
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Mohammad Reza Ghodraty
Position
Associate Professor of Anesthesiology department
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The personal information of the participants in the study is confidential and there is no need to publish it.

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

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

Title and more details about the data/document

Informed consent, Study protocol and details of methodology, Data files (SPSS) without specifying personal information, Data analysis tables and outputs.

When the data will become available and for how long

After completing the study and defending the residency thesis and sending the article to the journals for publication.

To whom data/document is available

Researchers and students interested in the subject, university and ministry officials, the magazine's editor-in-chief.

Under which criteria data/document could be used

Use to design additional studies, verification by officials and managers of journals.

From where data/document is obtainable

Corresponding author

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

Request via official letter or email

Comments