

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 P_{CO}2; 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 Ghodrati

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

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget 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

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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 two 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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Anesthesia Department, Firoozgar hospital, Beh-afarin St. Karim Khan Av.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abbas Motevalian MD.

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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**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodraty

Position

Associate Professor of Anesthesiology department

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

Iran University of Medical Sciences

Full name of responsible person

Elmira Sakhaeyan

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Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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

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Full name of responsible person

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Latest degree

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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