

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of volume control versus pressure control ventilation effects on the mechanical parameters of respiratory system and gas exchange during laparoscopic gastric bypass surgeries in obese patients

Protocol summary

Summary

The aim of this study is to compare the effects of two ventilation methods (Pressure VS volume control) on respiratory mechanics, quality of respiratory gases exchange and hemodynamic parameters of morbidly obese patients during laparoscopic bariatric operations. In a single blind randomized clinical trial, 60 patients candidated for laparoscopic bariatric surgery, with inclusion (BMI > 35 and 18 < age < 60 years) and exclusion (ASA class > III, inability of maintaining programmed ventilation protocol) criteria will be selected. After anesthesia induction for intraoperative ventilation, patients are to be rolled randomly in volume (VCV) or pressure (PCV) control ventilation groups. The intervention is as follows: In (VCV) group, patients will be ventilated with a tidal volume = 6-8 ml/ ideal BW and RR= 12/min. And in (PCV) group, inspiratory pressure will adjust to be delivered above tidal volume. Respiratory rate (RR) regulation will be used to keep the ET-CO2 between the ranges of 30-40 mmhg. Minute ventilation, exhaled tidal volume, peak and mean airway pressure, hemodynamic variables, peripheral blood oxygen saturation (SPO2), end of tidal CO2, will be recorded 5 min after intraperitoneal CO2 insufflation and then every 15 min during surgery. Arterial blood gas analysis are also to be checked two times with 30 min interval in the same period. Finally, the collected data will be put into evaluation and analysis using proper statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052711398N10**

Registration date: **2017-06-20, 1396/03/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-20, 1396/03/30

Registrant information

Name

Mohammad Reza Ghodrati

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

Iran University of Medical Sciences, IUMS

Expected recruitment start date

2017-06-06, 1396/03/16

Expected recruitment end date

2017-11-07, 1396/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of volume control versus pressure control ventilation effects on the mechanical parameters of respiratory system and gas exchange during laparoscopic gastric bypass surgeries in obese patients

Public title

Comparison of volume v/s pressure control ventilation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Body mass index more than 35 kg/m²; 18 < Age < 60; ASA class II- III; Consent for participation in the study
Exclusion criteria: 18 > Age > 60; Difficult Intubation; Inability to maintaining stable ventilator setting for 15 min; Inability to maintaining an appropriate ET-CO₂; Inability of extubation in the operating room; Change of surgical technique to open surgery; History of sever cardio-pulmonary disease; ASA class > III; Refusal of participation in the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

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

Hemmat highway

City

Tehran

Postal code

Approval date

2017-04-21, 1396/02/01

Ethics committee reference number

ir.iums.REC.1396.9411174013

Health conditions studied

1

Description of health condition studied

Morbid obesity

ICD-10 code

E66.8

ICD-10 code description

Other obesity

Primary outcomes

1

Description

Peak airway pressure

Timepoint

Every 15 min

Method of measurement

Anesthesia machine internal sensor

Secondary outcomes

1

Description

Dynamic compliance of respiratory system

Timepoint

Every 15 min

Method of measurement

Calculation by formula

2

Description

Arterial blood oxygenation

Timepoint

Two times with 30 min interval after starting of laparoscopy

Method of measurement

Arterial blood gas analysis

Intervention groups

1

Description

In the intervention group after induction of anesthesia & intubation, patients will be ventilated with pressure control mode. so the pressure will increase until ideal tidal volume (6-8 ml/kg) reached.

Category

Other

2

Description

In control group for mechanical ventilation during anesthesia, volume control mode will be used. Tidal volume set on 6-8 ml/kg of ideal body weight.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Mohammad Reza Ghodrati

Street address

Anesthesia ward, Firoozgar Hospital, Beh-Afarin St.
Karim Khan Av.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mehrdad Eftekhari MD.

Street address

Research deputy, Medicine Faculty, Hemmat highway

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Anesthesiologist, Faculty member

Other areas of specialty/work**Street address**

Anesthesia Ward, Firoozghar Hospital, Beh-Afarin St.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

mrghodrati@yahoo.com ghodrati.mr@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Faculty member, Associate Professor

Other areas of specialty/work**Street address**

Anesthesia Ward, Firoozgar Hospital, Beh-Afarin St.
Karim Khan Av.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

mrghodrati@yahoo.comghodrati.mr@iums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Sinadokht Tavoosian MD.

Position

Anesthesia Resident

Other areas of specialty/work**Street address**

Anesthesia Ward, Firoozgar Hospital, Beh-Afarin St.
Karim Khan Av.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

sina.tavoosian7@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty