

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of pressure controlled versus volume controlled mechanical ventilation on intraoperative oxygenation parameters of obese patients under laparoscopic Cholecystectomy

Protocol summary

Summary

The aim of study is to compare pressure controlled versus volume controlled mechanical ventilation on intraoperative oxygenation parameters of obese patients under laparoscopic Cholecystectomy. Obese patients with body mass index 30-40 and age 18-60 yr who has laparoscopic cholecystectomy will have spirometry before surgery. General anesthesia (balanced anesthesia) with standard monitoring will be used. Ventilator and oxygenation parameters will be taken every 15 min. At beginning of controlled ventilation, patients of both groups will ventilate by volume controlled ventilation with tidal volume 8cc/kg and inspiration: expiration (I/E) ratio 1:2 to maintain end expiratory CO₂ 35-40mmHg. After inducing pneumoperitoneum with intra-abdominal pressure of 10-12 mm Hg, patients will be positioned in 25 degree head up. Fifteen minute after pneumoperitoneum, patients randomly allocate in one of pressure controlled ventilation or volume controlled ventilation ventilator modes. Patients of both groups will have positive end expiratory pressure 5 cmH₂O in ventilator setting. After 15 min stabilization of pneumoperitoneum, Arterial blood gas is monitored and repeats every 20 min till end of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411213915N16**
Registration date: **2014-12-15, 1393/09/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-15, 1393/09/24

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor for Tabriz University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pressure controlled versus volume controlled mechanical ventilation on intraoperative oxygenation parameters of obese patients under laparoscopic Cholecystectomy

Public title

Comparison of pressure controlled versus volume controlled mechanical ventilation on intraoperative

oxygenation parameters of obese patients under laparoscopic Cholecystectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: obese patients with body mass index 30-40; American society of anesthesiologists class 1-2; age 18-60 yr; without restrictive or obstructive lung diseases. Exclusive criteria: prediction of extubation failure after surgery; intubation failure with routine practice; can not to maintain and stabilization of ventilatory setting after 30 minutes; inability to maintain adequate end expiratory CO₂; change of laparoscopy to open surgery.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2014-08-18, 1393/05/27

Ethics committee reference number

9385

Health conditions studied

1

Description of health condition studied

oxygenation status during laparoscopic colecystectomy

ICD-10 code

T80-T88

ICD-10 code description

Complications of surgical and medical care, not elsewhere classified

Primary outcomes

1

Description

Oxygenation and ventilatory parameters

Timepoint

Every 20 min till end of surgery

Method of measurement

Arterial Blood Gases

Secondary outcomes

empty

Intervention groups

1

Description

Group A: Pressure controlled ventilation 15 min after pneumoperitoneum

Category

Treatment - Devices

2

Description

Group B: Volume controlled ventilation 15 min after pneumoperitoneum

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr Ali Peirovifar

Street address

Golgasht Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor for Tabriz University of
Medical Sciences

Full name of responsible person

Dr Farhoodi

Street address

Golgasht street

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Vice Chancellor for Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ali Peirovifar

Position

Associate Professor

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Web page address**Person responsible for updating data****Contact****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