

# 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 CO<sub>2</sub> 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 cmH<sub>2</sub>O 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

Iran (Islamic Republic of)

###### Phone

+98 41 1526 2253

###### Email address

peirovifara@tbzmed.ac.ir

##### 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 CO<sub>2</sub>; 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

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

Operation room, Emam Reza Hospital, Golgasht street

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

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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*