Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Comparative evaluation of the effects of three different recruitment maneuvers during laparoscopic Bariatric surgeries of morbid obese patients on cardiopulmonary Indices

Protocol summary

Summary

Laparoscopic bariatric surgeries in morbid obese patients may be associated with atelectasis, hypercapnia and hypoxemia, intra and postoperatively. Several strategies are used for prevention of these consequences. This study is going to examine the effects of three different recruitment maneuvers comparatively during surgery and the influence of the maneuvers on some cardiopulmonary Indices. In a Clinical trial, 90 subjects of Laparoscopic surgery with body mass indexes (BMI) higher than 40 randomly divide into 3 equal groups. The first group subject to 10 cmH2O positive end expiratory pressure (PEEP) during surgery, the second group, after venting the pneumoperitoneum, take 5 deep breaths with positive pressure of 40 cmH2O and a 5-second pause and a 5-second Interval (Expiration) and the third group, take both. Pulmonary and hemodynamic parameters will measure every 15 minutes and compare between three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070316415N6**
Registration date: **2017-07-25, 1396/05/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

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Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-08-01, 1395/05/11

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effects of three different recruitment maneuvers during laparoscopic Bariatric surgeries of morbid obese patients on cardiopulmonary Indices

Public title

Effects of recruitment maneuvers on cardiopulmonary indices during laparoscopic bariatric surgeries of morbid obese patients

Purpose

Supportive

Inclusion/Exclusion criteria

Age 15-65 years old; ASA 1 and 2; BMI ≥ 40; no smoking; normal Intra cranial pressure; no pulmonary disease.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib Boulevard, Isfahan,

City

Isfahan

Postal code

Approval date

2015-09-09, 1394/06/18

Ethics committee reference number

IR.MUI.REC.1394.3.670

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.8

ICD-10 code description

Morbid obesity

Primary outcomes

1

Description

Heart rate, Blood pressure,Spo2

Timepoint

Each 15 minutes

Method of measurement

Measurement by anesthesia monitoring system

Secondary outcomes

1

Description

Secondary outcome measure 1 : Peak airway pressure, Plateu airway pressure

Timepoint

Each 15 minutes

Method of measurement

By ventilator of anesthesia mashine

Intervention groups

1

Description

First group: patients received 10 cmH2O PEEP from the beginning to the end of the surgery.

Category

Treatment - Other

2

Description

Second group: patients were received 5 breaths with positive pressure of 40 cmH2O with 5 seconds of pauses and 5 second intervals as expiration at the end of surgery and after venting pneumoperitoneum.

Category

Treatment - Other

3

Description

Third group: patients received 10 cmH2O PEEP from the beginning to the end of the surgery and after venting the abdomen patients were received 5 breaths with positive pressure of 40 cmH2O with 5 seconds of pauses and 5 second intervals as expiration

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical Center

Full name of responsible person

Golparvar M. MD

Street address

Department of Anesthesia, Alzahra Medical center, Sofeh boulevard, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Ali M Sabzghabaee
Street address
Research manager office, Deputy of research and technology, Isfahan University of Medical Sciences; Hezarjarib Boulevard, Isfahan, Iran
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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

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Name of organization / entity
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Person responsible for updating data

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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