Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of PI max on respiratory tract complications in patients under laparascopic bariatric surgeries

Protocol summary

Study aim
The effect of PI max(maximum inspiratory pressure) on respiratory tract complications in patients under laparascopic bariatric surgeries

Design
Fifty fore patients undergoing bariatric surgery were randomly divided into two groups of 27 each in the first group mechanical ventilation will be done with Positive end-expiratory pressure and in the second group without Positive end-expiratory pressure. Patients were randomly allocated into two groups with and without PEEP.

Settings and conduct
This study is a double blind study done in Al-Zahra Hospital in Isfahan during 2019. Patients and data collectors are unaware of the mechanism of mechanical breathing.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients undergoing barbaric surgery, age range of 18 to 55 years. Not inclusion criteria: patients with concomitant diseases, especially heart disease such as asthma, emphysema, chronic bronchitis, bronchitis, and pulmonary artery hypertension.

Intervention groups
Intervention group 1: mechanical ventilation volume control based on weight (Tidal Volume = 8 cc/kg)
Intervention group 2: Volume control mechanical ventilation with PEEP = 10 and 100% oxygen at 5 liters per minute

Main outcome variables
Length of stay in Intensive Care Unit (ICU), length of stay in ward, spo2, maximal airway pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130311012782N38**
Registration date: **2020-01-30, 1398/11/10**
Registration timing: **retrospective**

Last update: **2020-01-30, 1398/11/10**
Update count: **0**

Registration date
2020-01-30, 1398/11/10

Registrant information

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Ali Mehrabi kushki

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-22, 1396/06/31

Expected recruitment end date
2018-09-20, 1397/06/29

Actual recruitment start date
2018-09-22, 1397/06/31

Actual recruitment end date
2019-06-19, 1398/03/29

Trial completion date
2019-06-19, 1398/03/29

Scientific title
The effect of PI max on respiratory tract complications in patients under laparascopic bariatric surgeries

Public title
The Effect of Expiry End Air Pressure on Respiratory Complications of Patients Undergoing Gastric Surgery

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patient candidate for bariatric surgery Range age between 18 to 55 years Patient recruitment to participate in the study
Exclusion criteria:
Suffer to cardiovascular diseases
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**
Actual sample size reached: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients into two groups is done by using "Random Allocation Software". So that in terms of number of samples, the range is inserted into the software. Then the number of groups and the proportion of individuals in each group are determined. The software output is a two-part list with the first part of the number assigned randomly to group one, and the second list is the number assigned to the second group. According to the above list, patients are divided into two groups according to the time of entered to the study and continued until to reach of the required sample size in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double blind study. So that patients are aware of the mechanical ventilation they receive. The type of mechanical ventilation applied to the patient, including mechanical ventilation with PEEP and mechanical ventilation without PEEP, is performed for the patient, but the person collecting the data will be unaware about the type of mechanical ventilation applied.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Vice chancellor for research, Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2018-06-23, 1397/04/02
Ethics committee reference number
IR.MUI.MED.REC.1397.083

Health conditions studied

1

Description of health condition studied
Bariatric surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Respiratory Disorders
Timepoint
During and the end of surgery
Method of measurement
Pulse Oximeter

2

Description
Tidal Volume
Timepoint
During and the end of surgery
Method of measurement
Pulse Oximeter

3

Description
Blood Pressure
Timepoint
During and the end of surgery
Method of measurement
Pulse Oximeter

4

Description
Heart Bit
Timepoint

During and the end of surgery
Method of measurement
Pulse Oximeter

5

Description
stands for peripheral capillary oxygen saturation
Timepoint
During and the end of surgery
Method of measurement
Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, the mechanical ventilation of patients will be done based on the ideal weight of patients and tidal volume without applying Psitive End Expiratory Ventilation .
Category
Treatment - Devices

2

Description
Intervention group 2:In this group, the mechanical ventilation of patients will be done based on the ideal weight of patients and tidal volume with applying Positive End Expiratory ventilation and flow rate of 100% oxygen with 5 liters per minute.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Heidar Karimi
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Alzahra hospitail, Soffeh street, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Department of anesthesiology, Alzahra hospital, Soffeh street
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Heidar Karimi
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Resident of anethesiology
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Person responsible for updating data

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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 plan belongs to the state agency and cannot be shared.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available