

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Registration timing: **retrospective**

Study aim

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

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

Update count: **0**

Registration date

2020-01-30, 1398/11/10

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.

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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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.

Recruitment status

Recruitment complete

Funding source

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.

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

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N38**

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

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

Isfahan

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 Positive 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

Street address

Alzahra hospitail, Soffeh street, Isfahan

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heidarkarimi1975@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Position

Resident of anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Parvin Sajedi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

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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