

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Positive End Expiratory pressure during laryngeal mask airway anesthesia on respiratory parameters and abdominal pain in cataract surgery

Protocol summary

Study aim

Effects of positive expiratory end pressure during general anesthesia with airway laryngeal mask on ventilatory parameters and abdominal pain

Design

In this study, 80 patients between the age of 20 and 70 will be divided into two groups, divided into groups one and two of the American Society of Anesthesiologists (ASA Class I and II) who undergo cataract surgery.

Settings and conduct

The positive effects of expiratory end pressure during general anesthesia with airway laryngeal mask on ventilatory parameters and abdominal pain in cataract surgery in Nikokari hospital in Tabriz. In this double-blind study, researchers and data analysts are blind.

Participants/Inclusion and exclusion criteria

All patients aged 20 to 70 years with ASA Class I and II undergoing general anesthesia cataract surgery using a laryngeal mask. Exclusion criteria: - Surgery under local anesthesia - Lung disease - BMI > 30 Patients with obstructive sleep apnea - Patients with a history of gastroesophageal reflux - unwillingness to participate in the study

Intervention groups

For the first group, ventilation of PEEP-free volume control, ie, the current volume of 6 ml / kg based on ideal body weight, with a respiratory rate of 10-8 minutes per minute will begin. And then based on capnography and to maintain EtCo2 between 30 and 35 mmHg, the respiratory rate will change as needed. The second group will be treated exactly the same as the first group plus PEEP at 5 cmH2o. At anesthesia 1, 5, 10 and 20 minutes after anesthesia the peak pressure (PPeak), dynamic complement, expiratory volume, Spo2 (pulse oximetry), non-invasive blood pressure and heart rate will be recorded for all patients by anesthesiologist. . The information displayed on the MEDEC Saturn Evo

anesthesia machine will be used to record the above

Main outcome variables

Nausea, headache, back pain, respiratory depression

General information

Reason for update

Acronym

اثرات فشار مثبت

IRCT registration information

IRCT registration number: **IRCT20190921044832N1**

Registration date: **2019-11-30, 1398/09/09**

Registration timing: **prospective**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

Registration date

2019-11-30, 1398/09/09

Registrant information

Name

Jafar Rahimi panahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Positive End Expiratory pressure during laryngeal mask airway anesthesia on respiratory parameters and abdominal pain in cataract surgery

Public title
Effects of Positive End Expiratory pressure during laryngeal mask airway anesthesia on respiratory

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All patients aged 20 to 70 years with ASA Class I and II undergo general anesthesia cataract surgery using a laryngeal mask.
Exclusion criteria:
 - Surgery under local anesthesia People with mental disabilities Over 70 years old Under 20 years unwillingness to participate in the study Patients with a history of gastroesophageal reflux Patients with obstructive sleep apnea BMI> 30 Lung disease

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to intervention and control groups will be performed using the random numbered table technique via Randlist online software, individually for patients. In this study, patients were randomly divided into two groups via simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
The anesthesiologist is responsible for administering the anesthesia, monitoring the patient and preparing study solutions and is not blind to the autopsy. But the students are blind to the data analysis. The student is responsible for collecting patient information and variables.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, Daneshghah street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615953

Approval date

2019-10-28, 1398/08/06

Ethics committee reference number

IR.TBZMED.REC.1398.766

Health conditions studied

1

Description of health condition studied

In this study, patients were classified into groups one and two of the ASA Class I and II classifications undergoing cataract surgery.

ICD-10 code

H18.81

ICD-10 code description

Anesthesia and hypoesthesia of cornea

Primary outcomes

1

Description

Hypotension

Timepoint

Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

Method of measurement

Monitoring, Sphygmomanometer tool

2

Description

Respiratory depression

Timepoint

Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

Method of measurement

Monitoring, Sphygmomanometer tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: the process is exactly similar to control group. The positive end-expiratory pressure will be applied with 5cm of H₂O. 1, 5, 10 and 20 minutes after giving anesthesia, Peak inspiratory pressure, dynamic compliance, expiratory volume, SpO₂, Pulse oximetry, Noninvasive Blood Pressure and heart rate will be measured and recorded by anesthesiologist for all patients. The information will be displayed on Saturn Evo Anesthesia Machine that is used for recording the data. Recovering from anesthesia the patient will be transferred to recovery room

Category

Treatment - Drugs

2

Description

Control group: accreditation without PEEP, was added to 6 ml / kg and brewed at 5 ml / kg. And further, according to the guidelines of Copnography and EtCo₂ support between 30 and 35 mm Hg, please breathe so you can easily change.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Nikokari hospital

Full name of responsible person

Jafar Rahimi Panahi

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Nikokari hospital, Abasi square, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Jafar Rahimi Panahi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available