

# 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 EtCo<sub>2</sub> 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 cmH<sub>2</sub>O. At anesthesia 1, 5, 10 and 20 minutes after anesthesia the peak pressure (P<sub>Peak</sub>), dynamic complement, expiratory volume, Spo<sub>2</sub> (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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 1994

##### Email address

panahij@tbzmed.ac.ir

##### 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 H<sub>2</sub>O. 1, 5, 10 and 20 minutes after giving anesthesia, Peak inspiratory pressure, dynamic compliance, expiratory volume, SpO<sub>2</sub>, 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 EtCo<sub>2</sub> 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

##### Street address

Nikokari hospital, Abasi square, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

34424882

##### Phone

+98 41 3442 4425

##### Email

panahij@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. abolghasem jouyban

##### Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

3344280 0413

##### Phone

+98 41 3334 4280

##### Email

ajouyban@hotmail.com

##### 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

##### Street address

No32, University Ave, Opposite the Central Office of Tabriz University of Medical Sciences, Tabriz Town, IRAN

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

333333

##### Phone

+98 914 313 8969

##### Email

panahij@tbzmed.ac.ir

## Person responsible for scientific 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

**Street address**

No.32,University Ave, Opposite the Central Office of  
Tabriz University of Medical Sciences,Tabriz  
Town,IRAN

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

9999999999

**Phone**

+98 914 313 8969

**Email**

panahij@tbzmed.ac.ir

## Person responsible for updating data

### 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

**Street address**

No.32,University Ave., opposite the Central Office of  
Tabriz University of Medical Sciences,Tabriz  
Town,IRAN

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

3345697

**Phone**

3345697

**Email**

panahij@tbzmed.ac.ir

## 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