

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of Pressure-controlled inverse ratio ventilation during laryngeal mask airway anesthesia on ventilatory parameters

Protocol summary

Study aim

Comparison the effect of Pressure-controlled inverse ratio ventilation during laryngeal mask airway anesthesia on ventilatory parameters

Design

Clinical trial with parallel, randomized, and single-blind groups on 80 patients. Sealed envelopes were used for randomization.

Settings and conduct

This study was performed in the Anesthesiology Research Center of Tabriz University of Medical Sciences. The operating room nurse, who chooses sealed envelopes will be blinded about patients groups.

Participants/Inclusion and exclusion criteria

All patients aged 20 to 70 years with ASA class one and two who undergo cataract surgery under general anesthesia using a laryngeal mask will be included in the study.

Intervention groups

Group 1: Compression ventilation group with normal ratio ratio of inhalation to exhalation 1 to 2), maximum airway pressure will be adjusted so that the current volume of 6 ml/kg based on the ideal body weight is delivered to the patient's lungs and after starting Respiratory rate with 8 to 10 per minute, then the number of breaths to maintain carbon dioxide at the end of exhalation between 30 to 35 mm Hg will be changed as needed. Group 2: Compression ventilation group with inverse ratio (ratio of inhalation to exhalation 1.5 to 1), the maximum airway pressure will be adjusted so that the current volume of 6 ml/kg based on the ideal body weight is delivered to the patient's lungs and then From the beginning of the number of breaths with 8 to 10 per minute, then the number of breaths to maintain carbon dioxide at the end of the exhalation between 30 to 35 mm Hg will be changed as needed.

Main outcome variables

Maximum airway pressure, airway dynamic compliance, expiratory volume of exhalation, arterial blood oxygen

saturation, arterial blood pressure, heart rate, abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201109049319N1**

Registration date: **2020-12-10, 1399/09/20**

Registration timing: **retrospective**

Last update: **2020-12-10, 1399/09/20**

Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

Mahkam Rezvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3668 6556

Email address

mahkam.rezvani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

2020-05-21, 1399/03/01

Actual recruitment end date

2020-10-21, 1399/07/30

Trial completion date

2020-11-20, 1399/08/30

Scientific title

Effect of Pressure-controlled inverse ratio ventilation during laryngeal mask airway anesthesia on ventilatory parameters

Public title

Pressure-controlled inverse ratio ventilation during laryngeal mask airway anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA class one and two Candidate for cataract surgery under general anesthesia using laryngeal mask

Exclusion criteria:

Perform surgery under local anesthesia Lung disease BMI > 30 kg/m² Patients with obstructive sleep apnea Patients with a history of gastroesophageal reflux Reluctance to participate in the study Age under 20 years Age over 70 years People with mental disabilities

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be using sealed envelopes, of which 80 envelopes will be selected in total and will be divided into two groups of 40, including groups A and B. Envelopes will be selected by the operating room nurse who is blind to the study groups. Group A will be the usual pressure ventilation group, group B will be the reverse pressure ventilation group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The operating room nurse, who chooses sealed envelopes, will be blinded about patients groups.

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

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.TBZMED.REC.1398.708

Health conditions studied**1****Description of health condition studied**

Pressure-controlled inverse ratio ventilation during laryngeal mask airway anesthesia

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes**1****Description**

Maximum airway pressure

Timepoint

1, 5, 10 and 20 minutes after the start of anesthesia

Method of measurement

Ventilator device monitor

2**Description**

airway dynamic compliance

Timepoint

1, 5, 10 and 20 minutes after the start of anesthesia

Method of measurement

Ventilator device monitor

3**Description**

expiratory volume of exhalation

Timepoint

1, 5, 10 and 20 minutes after the start of anesthesia

Method of measurement

Ventilator device monitor

4

Description

arterial blood oxygen saturation

Timepoint

1, 5, 10 and 20 minutes after the start of anesthesia

Method of measurement

Ventilator device monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Compression ventilation group with normal ratio of inhalation to exhalation 1 to 2), maximum airway pressure will be adjusted so that the current volume of 6 ml/kg based on the ideal body weight is delivered to the patient's lungs and after starting Respiratory rate with 8 to 10 per minute, then the number of breaths to maintain carbon dioxide at the end of exhalation between 30 to 35 mm Hg will be changed as needed.

Category

N/A

2

Description

Intervention group: Compression ventilation group with inverse ratio (ratio of inhalation to exhalation 1.5 to 1), the maximum airway pressure will be adjusted so that the current volume of 6 ml/kg based on the ideal body weight is delivered to the patient's lungs and then From the beginning of the number of breaths with 8 to 10 per minute, then the number of breaths to maintain carbon dioxide at the end of the exhalation between 30 to 35 mm Hg will be changed as needed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikoukari hospital

Full name of responsible person

Dr. Jafar Rahimi

Street address

Nikukari hospital, in front of 11 Janbazan Police Station, Abbasi Street

City

Tabriz

Province

East Azarbaijan

Postal code

5154645395

Phone

+98 41 3657 7330

Email

nikohosp@tbzmed.ac.ir

Web page address

https://nikukarihosp.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ata Mahmoudpour

Street address

Faculty of medicine, near Imam-Reza hospital, Gholgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3336 4667

Email

amahmoodpoor@yahoo.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

Mahkam Rezvani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

Street address

Unit 10, First entrance, Negin 2 apartment, Kouhsar Blvd., Roshdiyeh Town

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3668 6556

Fax

Email

mahkam.rezvani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document

The request will be sent by email to person responsible for scientific or public inquiries.

Comments