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)
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+98 41 3668 6556
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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 Sceinces, 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 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
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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 enterance, Negin 2 apartment, Kouhsar Blvd., Roshdiyeh Town

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Person responsible for updating data

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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