Comparison of the effects of volume-controlled with pressure-controlled mechanical ventilation on blood loss in patients undergoing endoscopic sinus surgery

Protocol summary

Study aim
The key purpose of this study is to determine the impact of two mechanical ventilation mode "volume control & pressure control" on blood loss during endoscopic sinus surgery.

Design
Randomized clinical trial, with two parallel groups of 52 (group 1: mechanical ventilation with volume mode, group 2: mechanical ventilation with pressure mode). single blinded: the participants will be blind to the ventilation mode.

Settings and conduct
Patients who referred to the operating room in Kashan Matini Hospital for endoscopic sinus surgery will be enrolled. One group will receive volumetric ventilation with current volume 7ml/kg/IBW, 12 cycles per minute inspiration rate and inhale to exhale ratio 1:2 without PEEP, during the operation. The inspiration rate is altered to achieve end exhale carbon dioxide of 30-45 mm Hg. The other group will receive pressure ventilation with initial pressure 15 H2O/cm and 12 cycles per minute, and inhale to exhale ratio 1:2 without PEEP. Then the current volume will be adjusted to 7ml/kg/IBW by changing the pressure to achieve the end exhale carbon dioxide 35-40 mm Hg by changing the inspiration rate. Blood pressure and heart rate of the patients will be checked every 15 minutes after anesthesia.

Participants/inclusion and exclusion criteria
Patients who aged 15-75, with ASA class1or 2, nominated for endoscopic sinus surgery, informed about the study, and signed the informed consent from will be included in the study. Patients with chronic hypertension, respiratory problems, repeated surgery, emergency surgery, and coagulopathies, will be excluded.

Intervention groups
First group: mechanical ventilation with volume mode
Second group: mechanical ventilation with pressure mode

Main outcome variables
Intensity and volume of bleeding during the operation will be compared between two groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT2019040843202N1
Registration date: 2019-06-25, 1398/04/04
Registration timing: prospective

Last update: 2019-06-25, 1398/04/04
Update count: 0
Registration date
2019-06-25, 1398/04/04

Registrant information
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Seyed amir masoud Farzadfar
Name of organization/entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-13, 1398/05/22
Expected recruitment end date
2020-03-19, 1398/12/29
Actual recruitment start date
Comparison of the effects of volume-controlled with pressure-controlled mechanical ventilation on blood loss in patients undergoing endoscopic sinus surgery

Effect of ventilation mode on blood loss during endoscopic sinus surgery

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ASA class 1 & 2
Patients referred to operating room for endoscopic sinus surgery

Exclusion criteria:
Patients with chronic hypertension
Respiratory problems
Repeated surgery
Emergency surgery
Hemorrhagic diseases
Taking anti-coagulant medications
Patients who didn't sign the consent form

Age
From 15 years old to 75 years old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: 104

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining the informed consent, the enrolled patients will be randomly divided into two groups of 52. To achieve a balanced sample size across two groups, a permuted block randomization method will be used. We will make blocks with 4 and 6 samples for better randomization of groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The enrolled patients, will be blind to the mode of ventilation used during anesthesia. Clinician would be blind for measurement of outcome.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary outcomes

Primary outcomes

Description of health condition studied
Blood loss during endoscopic sinus surgery

ICD-10 code
ICD-10 code description

Secondary outcomes

Description of health condition studied

ICD-10 code
ICD-10 code description

Ethics committees

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences, Ghotb-e-Ravandi Blvd, Kashan, I. R. Iran

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2018-08-13, 1397/05/22

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.038

Health conditions studied

1

Description of health condition studied

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Surgical blood loss

Timepoint
End of surgery

Method of measurement
Measuring the amount of blood accumulated in suction instrument and absorbed by dressing gauzes in ml.

Secondary outcomes

1

Description
Hypotension

Timepoint
During the operation

Method of measurement
Continuous NIBP monitoring

2

Description
Surgeon's satisfaction with a bloodless field

Timepoint
At the end of surgery

Method of measurement
Surgeon’s satisfaction scoring system

3

Description
Number of infused blood bags

Timepoint
At the end of surgery

Method of measurement
Counting the number of infused blood bags

4

Description
Level of serum hemoglobin

Timepoint
Before starting the surgery and 6 hours after the end of the procedure

Method of measurement
Doing Complete Blood Cell (CBC) test on blood samples using cell counter.

Intervention groups

1

Description
Intervention group 1: during the surgery, this group will receive volumetric ventilation with a current volume of 7 ml/kg/IBW, inspiration rate of 12 cycles per minute and inhale to exhale ratio of 1:2 without PEEP and the inspiration rate is changed to achieve exhale end carbon dioxide of 35-40 mm Hg.

Category
Treatment - Other

2

Description
Intervention group 2: during the surgery, this group will receive pressure ventilation with the initial pressure of 15 H2O/cm, inspiration rate of 12 cycles per minute and inhale to exhale ratio 1:2 with no PEEP drops down. Then the current volume will be achieved to 7 ml/kg/IBW by changing the pressure and the exhale end carbon dioxide will reach to 35-40 mm Hg by changing the inspiration rate.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Matini Hospital

Full name of responsible person
Dr. Seyed amir masoud Farzadfar

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Sponsors / Funding sources

1

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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
Kashan 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
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Full name of responsible person
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Position
Anesthesiology resident

Latest degree
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Other areas of specialty/work
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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
No - There is not 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