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: IRCT20190408043202N1
Registration date: 2019-06-25, 1398/04/04
Registration timing: prospective

Registrant information
Name
Seyed amir masoud Farzadfar
Name of organization / entity
Country
Iran (Islamic Republic of)
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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

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 Ids
- empty

Ethics committees

1

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
- Isfahan

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
- Blood loss during endoscopic sinus surgery

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
Street address
Matini Hospital, Amirkabir Street, Kashan, Iran
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kashan University of Medical Sciences
Full name of responsible person
Seyed amir masoud Farzadfar
Position
Anesthesiology resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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