Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

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**

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

Registration date

2019-06-25, 1398/04/04

Registrant information

Name

Seyed amir masoud Farzadfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

farzadfar-am@kaums.ac.ir

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

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effect of ventilation mode on blood loss during endoscopic sinus surgery

Purpose

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 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

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

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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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
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Person responsible for scientific inquiries

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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