Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparative study of the effects of Sevoflurane and Isoflurane on bleeding rate during endoscopic surgery of nasal sinus

Protocol summary

Study aim
Detemine the effect of Sevoflurane and Isoflurane on bleeding rate of functional endoscopic sinus surgery.

Design
A triple blind randomized clinical trial assigned in two parallel 23 patients group

Settings and conduct
The patients referring to Sanandaj Kowsar Hospital for endoscopic sinus elective surgery to determine the effect of Sevoflurane and isoflurane on bleeding rate of this surgery was done.This randomly allocation and provision of anesthetic medicines is done by an anesthetist who will not interfere with the process of work and outcome measurements. Surgery is then performed by an ENT (ears, nose and throat) doctor with a surgical board.

Participants/Inclusion and exclusion criteria
Study inclusion criteria: All elective patients between 18 and 60 years old who have ASA 1, 2 and undergo elective FESS surgery. The study exclusion criteria: BMI≥30, history of alcohol or drug use, pregnancy, medications that affect MAC, communication problems, fungal sinusitis or nose polyps greater than 3 (due to increased inflammation and vascularity of the vessels that both cause increasing bleeding in the surgical field and Surgery Grade Score). It should be noted that all effective factors affect the amount of bleeding and evaluation and will be excluded during the study.

Intervention groups
Patients were entered in two groups, Sevoflurane group and Isofurane group with simple randomization.

Main outcome variables
Compression of the effects of Sevoflurane and Isoflurane on bleeding rate during endoscopic surgery of nasal sinus

General information

Reason for update

Acronym
FESS

IRCT registration information
IRCT registration number: **IRCT20120801010471N3**
Registration date: **2018-08-05, 1397/05/14**
Registration timing: **retrospective**

Last update: **2018-08-05, 1397/05/14**
Update count: **0**

Registration date
2018-08-05, 1397/05/14

Registrant information

Name
Milad Masaeli

Name of organization / entity
Kurdistan University Of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-11-21, 1395/09/01

Expected recruitment end date
2018-01-21, 1396/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effects of Sevoflurane and Isoflurane on bleeding rate during endoscopic surgery of

nasal sinus

Public title
Comparative study of the effects of Sevoflurane and Isoflurane on bleeding rate during endoscopic surgery of nasal sinus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elective surgery Patients between 18 and 60 years old ASA 1,2
Exclusion criteria:
BMI≥30 Alchohol user Medications that affect MAC Communication problems Fungal sinusitis Nasal polyps greater than 3 (due to increased inflammation and vascularity of the vessels that both cause increasing bleeding in the surgical field and Surgery Grade Score) Substance user
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **46**
More than 1 sample in each individual
Number of samples in each individual: **23**
23 patients will be assigned to each group.Group Isoflurane and group Sevoflurane.
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization based on random number table was done dividing patients into Isofloran and Sevofloran groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The researcher and surgeon were blinded by using covered vaporizers. The anesthetist knew the type of volatile, filled the questionnaire was not blinded.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee Of Kurdistan University Of Medical Science
Street address
Pasdaran
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Approval date
2017-05-28, 1396/03/07
Ethics committee reference number
IR.MUK.REC.1396/36

Health conditions studied

1

Description of health condition studied
Effect of sevoflurane and isoflurane on bleeding rate of functional endoscopic sinus surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Bleeding rate on endoscopic sinus surgery
Timepoint
The measurement of the amount of bleeding is evaluated with the mass of used sterilized gases using a calibrated scale each day and the amount of blood accumulated in the suction in cc .and after 60 minutes through Grade Score, the surgeon also evaluates the amount of bleeding during the surgery.
Method of measurement
Grade Assessment : 0 = No bleeding (Cadaveric conditions). 1= Slight bleeding - no suctioning required. 2= Slight bleeding - occasional suctioning required.3 = light bleeding - frequent suctioning required; bleeding threatens surgical field a few seconds after suction is removed

Secondary outcomes

empty

Intervention groups

1

Description
23 patients will be assigned to each group. Continuous clinical monitoring is performed with EKG, Pulse Oximetry, temperature, BP for every 3 minutes and

Bispectral Index (A 2000 BIS_XP, aspect medical system INC, Norwood, MA, USA). The patients' height and weight in both groups will be evaluated at the beginning of the entry by similar devices and an anesthetics assistance. Subsequently, 5 minutes before initiation of induction, 5 mg / kg of ringer is administered. Then, 2 µ / kg of fentanyl, 0.15 mg / kg midazolam, 1 mg / kg lidocaine, 8 mg dexamethasone, and 10 mg of metoclopramide were injected in 5 minutes to the patients. Then, propofol at a dose of 2 mg / kg is administered for induction in 30 seconds. During induction, 100% oxygen was inducted to the patients. After the disappearance of lash reflex, a dose of 0.5 mg / kg bolus atracurium was injected for muscle relaxation in 30 seconds. Intracranial intubation is performed with spiral tube number 7 for women and 7.5 for men. After intubation, mechanical ventilation to reach End tidal is set Co2 25-35 mm / Hg with 50% O2 + N2O and the volume of 8cc / kg and I / E: 1/2 and peep: 0 and RR: 12. In isoflurane group is given 1 MAC during inhalation anesthetics' operation. Our goal is to reach MAP: 65 and HR: 85. And if MAP is lower than 60, 5 mg of Ephedrine bolus is prescribed. If MAP is more than 85, 50 micrograms of TNG will be injected. No other medicine will be prescribed. If for any reason we have to use another medicine, or change the patient's ventilation, and if the operation has an effect on the amount of bleeding, the patient is excluded from the study and at the end of the project, the paper will record the cause. During surgery, every 30 minutes, according to the amount of TOF, non-depolarizing muscle relaxation will be repeated based on narcotic BIS. Immediately after the completion of surgery, all medicines will be discontinued except oxygen, and the patient will be extubated after airway reflexes.

Category

Other

2

Description

Control group: 23 patients will be assigned to this group. Continuous clinical monitoring is performed with EKG, Pulse Oximetry, temperature, BP for every 3 minutes and Bispectral Index (A 2000 BIS_XP, aspect medical system INC, Norwood, MA, USA). The patients' height and weight in both groups will be evaluated at the beginning of the entry by similar devices and an anesthetics assistance. Subsequently, 5 minutes before initiation of induction, 5 mg / kg of ringer is administered. Then, 2 µ / kg of fentanyl, 0.15 mg / kg midazolam, 1 mg / kg lidocaine, 8 mg dexamethasone, and 10 mg of metoclopramide were injected in 5 minutes to the patients. Then, propofol at a dose of 2 mg / kg is administered for induction in 30 seconds. During induction, 100% oxygen was inducted to the patients. After the disappearance of lash reflex, a dose of 0.5 mg / kg bolus atracurium was injected for muscle relaxation in 30 seconds. Intracranial intubation is performed with spiral tube number 7 for women and 7.5 for men. After intubation, mechanical ventilation to reach End tidal is set Co2 25-35 mm / Hg with 50% O2 + N2O and the volume of 8cc / kg and I / E: 1/2 and peep: 0 and RR: 12. In sevoflurane group is given 1 MAC during inhalation anesthetics' operation. Our goal is to reach MAP: 65 and HR: 85. And if MAP is lower than 60, 5 mg of Ephedrine bolus is prescribed. If MAP is more than 85, 50 micrograms of TNG will be injected. No other medicine will be prescribed. If for any reason we have to use another medicine, or change the patient's ventilation, and if the operation has an effect on the amount of bleeding, the patient is excluded from the study and at the end of the project, the paper will record the cause. During surgery, every 30 minutes, according to the amount of TOF, non-depolarizing muscle relaxation will be repeated based on narcotic BIS. Immediately after the completion of surgery, all medicines will be discontinued except oxygen, and the patient will be extubated after airway reflexes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Milad Masaeli

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Kowsar Hospital, Pasdaran Ave, Sanandaj

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http://www.muk.ac.ir/Muk/Hospitals/kawsar/contact/Contact.aspx

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Farzin Rezaii

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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
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Milad Masaeli
Position
Resident of Anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
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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
Yes - There is 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
All of the data Provided except private data of patients
When the data will become available and for how long
After the submission of the article in a valid journal
To whom data/document is available
This is available for any researchers who interested in subject .

Under which criteria data/document could be used

Any new research based on our date with cooperation would be available .

From where data/document is obtainable

Dr.Milad Masaeli

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

The available data should be asked in an email to let me know how i can help with this

Comments