

# 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

Determine 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  $\geq$  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 Isoflurane group with simple randomization.

##### Main outcome variables

Comparison 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)

###### Phone

+98 87 3356 5240

###### Email address

drmilmas@muk.ac.ir

##### 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 $\geq$ 30 Alcohol 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

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#### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Kowsar Hospital

##### **Full name of responsible person**

Milad Masaeli

##### **Street address**

Kowsar Hospital, Pasdaran Ave, Sanandaj

##### **City**

Sanandaj

##### **Province**

Kurdistan

##### **Postal code**

66177-13446

##### **Phone**

+98 87 3361 1231

##### **Email**

drmilmas@yahoo.com

##### **Web page address**

<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

##### **Street address**

Kurdistan University Of Medical Science, Pasdaran Blv, Sanandaj

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drmilmas@yahoo.com

**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**  
Anesthesiology

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Kowsar Hospital, Pasdaran ave, Sanandaj

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Other areas of specialty/work**  
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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 data 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**