

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of bleeding during anesthesia with isoflurane and sevoflurane in endoscopic nasal surgeries and tympanomastoidectomy

Protocol summary

Summary

Objectives: In ear, nose and throat surgeries, like all types of surgeries anesthesiologists play an important role in an accurate and uncomplicated operation. Sinus endoscopy and tympanoplasty can be performed without anesthesia but in most cases, local or general anesthesia are needed for patient and surgeon comfort and reduce the surgery complications which bleeding is the most common of them. Sevoflurane is a fairly new inhalation anesthetic. Although it is like other inhaled anesthetic agents such as isoflurane but there are differences between them, including the rise in heart rate in anesthetized with isoflurane that does not happen with sevoflurane. Because the combination of remifentanyl and anesthetic gases is a proper method to controlled hypotension, we decided to compare these two drugs in sinus endoscopic surgery and tympanoplasty. Design: Block randomization, without placebo, trial phase 2, including ninety patients under sinus endoscopic surgery or tympanomastoidectomy Participants including major eligibility criteria: All the patients who underwent endoscopic sinus surgery or tympanomastoidectomy Intervention: Intervention 1. Sevoflurane, 1 MAC, inhalation, peri-operative Intervention 2. Isoflurane, 1 MAC, inhalation, peri-operative Main outcome measures: bleeding, blood pressure, heart rate, O2 saturation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306083289N6**

Registration date: **2014-01-17, 1392/10/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-17, 1392/10/27

Registrant information

Name

Esmail Moshiri

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

dr_moshiri@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak university of medical sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of bleeding during anesthesia with isoflurane and sevoflurane in endoscopic nasal surgeries and tympanomastoidectomy

Public title

Comparison of isoflurane and sevoflurane in nasal surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All the patients who underwent

endoscopic sinus surgery or tympanomastoidectomy
 Exclusion criteria: 1. Age over 55 years 2. Patients with history of cardiovascular problems, hypertension, and COPD 3. Patients under anticoagulation treatment 4. Using tranquilizers 5. Patients with drug abuse

Age
 From **18 years** old to **55 years** old

Gender
 Both

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 ninety patients candidate for nasal endoscopic surgeries and tympanoplasty divided into two equal groups using a randomized block.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

91-137-6

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

Y60.0

ICD-10 code description

Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care(During surgical operation)

Primary outcomes

1

Description

Bleeding

Timepoint

In the end of surgery

Method of measurement

Quality grading that is recorded in patient's sheet

2

Description

Blood pressure

Timepoint

At the beginning of operation and every 15 minutes during surgery.

Method of measurement

Measure with mercury sphygmomanometer and record in patient's sheet

3

Description

Heart rate

Timepoint

At the beginning of operation and every 15 minutes during surgery.

Method of measurement

The number of heart beats per minute is calculated and recorded in the patient's sheet

4

Description

Arterial saturation of oxygen

Timepoint

At the beginning of operation and every 15 minutes during surgery.

Method of measurement

Measure with pulse oximeter and record in patient's sheet

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Inhalational Sevoflurane, chemical composition 1,1,1,3,3,3-hexafluoro-2-(fluoromethoxy)propane, marketed by Abbot Park, North Chicago, Illinois, which is used by 1 MAC, peri-operative.

Category

Treatment - Other

2

Description

Intervention 2: Inhalational Isoflurane, chemical composition 1-chloro-2,2,2-trifluoromethyl ether, marketed by Nicholas Piramal(I)London, which is used by 1 MAC, peri-operative.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Dr Esmaeil Moshiri

Street address

Amirkabir Hospital. Parastar square. Arak. Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences,Vice Chancellor for Research

Full name of responsible person

Dr Saeed Changizi Ashtiani

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences,Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Esmaeil Moshiri

Position

Anesthesiologist, assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Esmaeil Moshiri

Position

Anesthesiologist, assistant professor

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

Dr Esmaeil Moshiri

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty