Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of isoflurane on bleeding and hemodynamic changes in patiants undergoing endoscopic sinus surgery

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is effect of isoflurane on bleeding and hemodynamic changes in patients under going endoscopic sinus surgery. Total of sample size is 90 patient with ages: 18-50 years old. Inclusion criteria are patients candidate for sinus surgery. The patients with heart disease, liver disease, drug allergy to isoflurane gas will be excluded. Patients are randomly divided into three groups with table of random numbers by computer. Assessor of study and patients do not know about type of drug and grouping people. Anesthesia induction in three groups is with with 0.05 mg/kg midazolam, 2 mcg/kg fentanyl, 5 mg thiopental sodium and 0.5 mg/kg atracurium. All three groups receives 0.1 mcg/kg/min remifentanil infusion. Maintenance of anesthesia in the first group is 0.8 MAC of isoflurane. Maintenance of anesthesia in the second group is 1 MAC of isoflurane. Maintenance of anesthesia in the third group is 1.2 MAC of isoflurane. Patients basic information such as age and sex, BMI will be recorded in all three groups before intervention and after the end of intervention period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011526025N1**
Registration date: **2016-02-04, 1394/11/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-04, 1394/11/15

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-10-18, 1394/07/26

Expected recruitment end date

2016-03-17, 1394/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of isoflurane on bleeding and hemodynamic changes in patiants undergoing endoscopic sinus surgery

Public title

the effect of Isoflurane anesthesia gas on blood circulation and bleeding in patients undergoing surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients candidate for sinus surgery; ASA (American society of anesthesiology) physical class one and two; Patient with ages: 18-50 years old.
Exclusion Criteria: History of kidney problems; Heart

disease; Liver disease; Drug allergy to isoflurane; Lack of patient satisfaction.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address
Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City
Ahvaz

Postal code

Approval date
2015-10-17, 1394/07/25

Ethics committee reference number
IR.AJUMS.REC.1394.395

Health conditions studied

1

Description of health condition studied
Intraoperative bleeding

ICD-10 code
Y60

ICD-10 code description
Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care

Primary outcomes

1

Description
Body mass index (BMI)

Timepoint
Before the start of surgery

Method of measurement
Using the formula: weight (kg) / the square of the height (m)

2

Description
The amount of hemoglobin

Timepoint
Immediately before surgery and immediately after surgery and 6 hours after surgery

Method of measurement
Venous sampling and sent to the laboratory

3

Description
The amount of hematocrit

Timepoint
Immediately before surgery and immediately after surgery and 6 hours after surgery

Method of measurement
Venous sampling and sent to the laboratory

4

Description
Bleeding (By calculating the difference between pre- and postoperative hemoglobin(Hb))

Timepoint
After surgery

Method of measurement
Using the formula: CBL= BV×(Hb loss/Hb per), Hb loss = Hb pre – Hb post + t (The number of injected packed red blood cell units)

5

Description
Bleeding (By calculating the difference between pre- and postoperative hematocrit(Hct))

Timepoint
After surgery

Method of measurement
Using the formula: CBL = RBCL / [(HCTper+HCTpost)/2], RBCL = BV × (Hct pre – Hct post) + 320 t

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 2: Prescription 1.2 MAC of isoflurane as a maintenance of anesthesia during surgery.
Category
Prevention

2

Description
Control group: Prescription 0.8 MAC of isoflurane as a maintenance of anesthesia during surgery.
Category
Prevention

3

Description
Intervention group1: Prescription 1 MAC of isoflurane as a maintenance of anesthesia during surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khomeini Hospital
Full name of responsible person
Ali Ghomeishi
Street address
Khomeini Hospital, Shahid Ahvazian St., Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Nader Saki
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City
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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
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
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
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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