

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of isoflurane on bleeding and hemodynamic changes in patients 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 undergoing 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 remifentanyl 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

Artadokht Khoshooei

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2922

Email address

khoshooei.a@ajums.ac.ir

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 patients 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: $CBL = BV \times (Hb \text{ loss} / Hb \text{ per})$, $Hb \text{ loss} = Hb \text{ pre} - Hb \text{ post} + t$ (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: $CBL = RBCL / [(HCT_{\text{pre}} + HCT_{\text{post}}) / 2]$, $RBCL = BV \times (Hct \text{ pre} - Hct \text{ post}) + 320 t$

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

City

Ahvaz

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

Street address

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

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

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Artadokht Khoshooei

Position

Resident of anesthesiology

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

Ar_khoshooei@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Reza Akhondzadeh

Position

anesthesiologist

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

rezaakh@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sanaz Nazari

Position

Nurse Anesthesia

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
GolestanBLvd., Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 3222 2922

Fax**Email**

s.nz1990@yahoo.com

Web page address**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