

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Sep 2026

Comparison of surgical condition and bleeding during propofol or isofluran anesthesia for endoscopic sinus injury

Protocol summary

Summary

Various maneuvers are used to achieve the ideal operative field necessary for successful endoscopic sinus surgery and decreased complications. controlled hypotension is one way that used to improve surgical conditions during endoscopic sinus surgery (mean arterial pressure 60-70mmHg) short acting anesthetics such as propofol and remifentanil allow control of intraoperative deliberated hypotension and thus might be valuable tools to compare with (traditional) balanced anesthesia. The aim of this study is to compare the surgical field in patients in whom intravenous anesthesia is used as apposed to balanced general anesthesia. For this reason in a patient-observer blind randomized clinical trial 44 patients from 15 to 45 years old that scheduled for endoscopic sinus surgery will select (after explaining the process of the trial, written informed consent obtained from participants). Then they will divide into two groups randomly, for the first group total intravenous anesthesia propofol 50mic/ kg/min+ remifentanil 0.1 mic/kg/min), second group (Isofluran 0.6%) and surgical condition and intraoperative bleeding will be recorded and then analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102081138N7**

Registration date: **2011-03-14, 1389/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-03-14, 1389/12/23

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2010-06-13, 1389/03/23

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of surgical condition and bleeding during propofol or isofluran anesthesia for endoscopic sinus injury

Public title

Comparison of propofol or isofluran anesthesia for sinus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidated for elective endoscopic sinus surgery (15-45yr); ASA class I,II; Patients with completely treated nose and sinus

infections Exclusion criteria: History of hemorrhagic disease; Seizure; Drugs that affect on the surgical homeostasis; Anemia (Hb <10); Poor controlled cerebrovascular accident; History of significant CAD; Arrhythmia; Liver or kidney dysfunction; Electrolyte or metabolic abnormalities; COPD; Severe asthma or other severe respiratory disease; History of PUD; Pregnancy

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Guilan University of Medical Sciences

Street address

Siadati st.

City

Rasht

Postal code

Approval date

2010-06-12, 1389/03/22

Ethics committee reference number

572

Health conditions studied

1

Description of health condition studied

Chronic Sinusitis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis, unspecified

Primary outcomes

1

Description

Surgical field condition

Timepoint

Every 15 minutes

Method of measurement

With table

Secondary outcomes

1

Description

Intraoperative bleeding percent

Timepoint

Every 15 minutes Intraoperatively

Method of measurement

Maximum allowable blood loss formula

Intervention groups

1

Description

Group A) propofol (50/mg/kg/min) + remifentanyl (0/1 mg/kg/min) group

Category

Treatment - Drugs

2

Description

Group B) Insofluran group (0-0/6%)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Sudabeh Haddadi

Street address

17 Shahrivar st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Susan Komaii

Street address

Siadati st.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Dr Sudabeh Haddadi

Position

Assistant professor

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Web page address**Person responsible for updating data****Contact****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