

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 deliberate 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) Isofluran 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.

##### City

Rasht

## 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

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

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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*