

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the effect of two different anesthesia methods with Remifentanyl and Dexmedetomidine on the amount of bleeding during surgery and the visual in endoscopic sinus surgeries

#### Protocol summary

##### Study aim

Comparison of the effect of two different anesthesia methods with Remifentanyl and Dexmedetomidine on the amount of bleeding during surgery and the visual in endoscopic sinus surgeries

##### Design

This study will be done in the operating room. All of the drugs solution of this study will be prepared by only one person who is aware of the study's grouping, in similar 50ml syringes and the same shape. Anesthesiologist, patients, and all medical staff that will collaborate in the study will not aware of the drug allocated to each patient.

##### Settings and conduct

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 40 patients who are candidates for sinus endoscopy will be enrolled. Eligible patients will be randomly allocated into two equal A and B groups by block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients between 18 and 60 years old with ASA grade I or II, who are candidates for sinus endoscopy. Exclusion criteria: allergy to the drugs used in the study and Positive history of kidney, liver, addiction and bleeding diseases.

##### Intervention groups

Intervention group: The surgical technique is the same for all patients and will be performed by a specific surgeon, but two different anesthetic formulas are used. Remifentanyl is started at an intravenous infusion rate of 0.25 µg/kg simultaneously with induction of anesthesia. Control group: The surgical technique is the same for all patients and will be performed by a specific surgeon, but two different anesthetic formulas are used. Dexmedetomidine 1µg/kg intravenous bolus dose during 20 minutes before induction of anesthesia and then continue with infusion rate of 0.4-0.8µg/kg/hr

simultaneously with induction of anesthesia.

##### Main outcome variables

Bleeding during surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240916063055N1**

Registration date: **2024-10-10, 1403/07/19**

Registration timing: **prospective**

Last update: **2024-10-10, 1403/07/19**

Update count: **0**

##### Registration date

2024-10-10, 1403/07/19

##### Registrant information

##### Name

Nima Naderi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3628 1460

##### Email address

naderin@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-11-01, 1403/08/11

##### Expected recruitment end date

2025-08-01, 1404/05/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of two different anesthesia methods with Remifentanyl and Dexmedetomidine on the amount of bleeding during surgery and the visual in endoscopic sinus surgeries

**Public title**

Comparison of the effect of two different anesthesia methods with Remifentanyl and Dexmedetomidine on the amount of bleeding during surgery and the visual in endoscopic sinus surgeries

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Adult patients with ASA grade I or II (American Society of Anesthesiology classification) Adult patients between 18 and 70 years old Adult patients who are candidates for sinus endoscopy

**Exclusion criteria:**

Allergy to the drugs used in the study Positive history of kidney, liver, addiction and bleeding diseases. Obesity (BMI > 40)

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly allocated into 2 groups by block randomization. In this technique, 5 blocks of size 4, 6, and 8 will be selected randomly for patients of 2 groups A and B. patients will be allocated randomly and equally into 2 groups. block sequence will be prepare by [www.sealedenvelope.com](http://www.sealedenvelope.com)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Drugs are provided in the form of similar 50ml syringes by the first person, these drugs, which have the same color and size and in similar colors, are injected by the second person who is completely unaware of the contents of the syringes. The anesthesiologist, patients, and other personnel involved in the work are blinded to the drugs injected in this study. This study is double-blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz Medical School.

**Street address**

3rd Floor, 3rd bBuiding of the Shiraz Medical School, Zand Blvd.

**City**

Shiraz

**Province**

Fars

**Postal code**

713451978

**Approval date**

2024-05-04, 1403/02/15

**Ethics committee reference number**

IR.SUMS.MED.REC.1403.080

**Health conditions studied****1****Description of health condition studied**

Endoscopic sinus

**ICD-10 code**

J32

**ICD-10 code description**

Chronic sinusitis

**Primary outcomes****1****Description**

Bleeding during surgery

**Timepoint**

During the surgery

**Method of measurement**

Based on the estimate of sterile gases used and Measuring the volume of the suction device

**2****Description**

postoperative nausea and vomiting

**Timepoint**

Recovery and at the time of arrival and every 30 minutes

**Method of measurement**

Based on scoring (0=no nausea and vomiting, 1=nausea,

2=vomiting and 3=vomiting more than 2 times)

### 3

#### **Description**

Pain after surgery

#### **Timepoint**

Recovery and at the time of arrival and every 20 minutes

#### **Method of measurement**

Visual pain scale questionnaire

### 4

#### **Description**

Blood pressure

#### **Timepoint**

During surgery every 15 minutes

#### **Method of measurement**

Monitoring

### 5

#### **Description**

heart rate

#### **Timepoint**

During surgery every 15 minutes

#### **Method of measurement**

Monitoring

### 6

#### **Description**

Consent of the surgeon

#### **Timepoint**

After surgery

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The surgical technique is the same for all patients and will be performed by a specific surgeon, but two different anesthetic formulas are used. Remifentanyl (Elixir Pharmaceutical Company) is started at an intravenous infusion rate of 0.25 µg/kg simultaneously with induction of anesthesia. After that, Midazolam (Aborehan Pharmaceutical Company) 0.04mg/kg, Fentanyl (Jahan Behbohd Company) 2µg/kg and Morphine (Alborz Daro Pharmaceutical Company) 10mg/kg as premedication and Propofol (Terman Yab Daro Company) 2-2.5µg/kg and Atracurium(Daro Pakhsh Company) 0.15mg/kg will be used to induce anesthesia. Maintenance is started with Propofol (100µg/kg/min).

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: The surgical technique is the same for all patients and will be performed by a specific surgeon, but two different anesthetic formulas are used.

Dexmedetomidine (Arang daro darman Company) 1µg/kg intravenous bolus dose during 20 minutes before induction of anesthesia and then continue with infusion rate of 0.4-0.8µg/kg/hr simultaneously with induction of anesthesia. After that, Midazolam (Aborehan Pharmaceutical Company) 0.04mg/kg, Fentanyl (Jahan Behbohd Company) 2µg/kg and Morphine (Alborz Daro Pharmaceutical Company) 10mg/kg as premedication and Propofol (Terman Yab Daro Company) 2-2.5µg/kg and Atracurium(Daro Pakhsh Company) 0.15mg/kg will be used to induce anesthesia. Maintenance is started with Propofol (100µg/kg/min).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Dastgheib Hospital

##### **Full name of responsible person**

Seyyed Farnoosh Firouzi

##### **Street address**

Hafez St

##### **City**

شیراز

##### **Province**

Fars

##### **Postal code**

7145683769

##### **Phone**

+98 71 3228 8064

##### **Email**

dastlib@sums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Khalili Hospital

##### **Full name of responsible person**

Seyed Farnoosh Firouzi

##### **Street address**

Khalili St.

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7193616641

##### **Phone**

+98 71 3629 1470

##### **Email**

khalili@sums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Hashem Hashempur

**Street address**

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3235 7282

**Email**

hashempur@gmail.com

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

No

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Farnoosh Firouzi

**Position**

Anesthesiology resident/physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3647 4270

**Email**

f.firoozi199@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Nima Naderi

**Position**

Assistant Professor of Pediatric Anesthesiology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7193711351

**Phone**

+98 71 3647 4270

**Email**

nima\_naderi0f@yahoo.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hamide Saeedizade

**Position**

Research Assisstant

**Latest degree**

Bachelor

**Other areas of specialty/work**

Medical Informatics

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

009836281460

**Email**

saeedi.hamide@gmail.com

## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

It is against our policy.

### **Study Protocol**

No - There is not a plan to make this available

### **Statistical Analysis Plan**

No - There is not a plan to make this available

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

No - There is not a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

No - There is not a plan to make this available