

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Sep 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

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.firoozi1990@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_naderi@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 Assistant

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