Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effect of two different anesthesia methods with Remifentanil 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 Remifentanil 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. Remifentanil 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)

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+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 Remifentanil 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 Remifentanil 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. Remifentanil (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
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
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Seyed Farnoosh Firouzi
Position
Anesthesiology resident/physician
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Person responsible for updating data

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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