Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Comparison of the effect of dexmedetomedine and remifentanil in reducing paranasal sinus surgery bleeding: a double-blind randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of dexmedetomedine and remifentanil in reducing paranasal sinus surgical bleeding

Design

A clinical trial with a control group, parallel groups, double-blind, randomized, phase 3 per 100 patients. Computer-generated random numbers will be used for randomization.

Settings and conduct

This study was designed to compare the effect of dexmedetomidine and remifentanil on reducing surgical bleeding in patients undergoing paranasal sinus and septoplasty and rhinoplasty, who were referred to Kowsar Hospital in Sanandaj After dividing the patients by randomization method and generating computer random numbers, patients in intervention group 1, dexmedetomidine at a dose of 0.2 µg / kg / h and patients in intervention group 2, remifentanil at a dose of 0.25 µg / kg / min by infusion Will receive. In order to blind the study, patients, specialist physicians and patient evaluators are not aware of the grouping of patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 45 years; Patient in class 1 or 2 ASA physical status; Patients who have been referred for paranasal sinus surgery, septoplasty, and rhinoplasty. Exclusion criteria: History of heart disease, hypertension, kidney, liver, lung and blood coagulation disorders; History of mental health problems; Patients receiving antihypertensive drugs Patients receiving NSAIDs; Patients with a BMI greater than 30.

Intervention groups

Group 1 intervention: After anesthesia in a similar plan, group A patients will receive dexmedetomidine at a dose of 0.2 µg / kg per hour as an infusion. Intervention group 2: After anesthesia in a similar plan, patients in group B will receive remifentanil at a dose of 0.25 µg / kg / min as an infusion.

Main outcome variables

Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220222054094N1**
Registration date: **2022-02-27, 1400/12/08**
Registration timing: **prospective**

Last update: **2022-02-27, 1400/12/08**
Update count: **0**

Registration date

2022-02-27, 1400/12/08

Registrant information

Name

Negin Maghsoumi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3361 1231

Email address

maghsouminegin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of dexmedetomedine and remifentanil in reducing paranasal sinus surgery bleeding: a double-blind randomized clinical trial

Public title

Comparison of the effect of dexmedetomedine and remifentanil in reducing paranasal sinus surgery bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 45 years Patient in class 1 or 2 ASA physical status Patients who have referred for para-nasal sinus surgery, septoplasty and rhinoplasty

Exclusion criteria:

History of heart disease, hypertension, kidney, liver and lung and blood coagulation disorders History of mental health problems Patients receiving anti-hypertensive drugs Patients receiving NSAIDs Patients with a BMI greater than 30

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done randomly using computer generated random numbers. Thus, each "odd number" produced belongs to group 1 (intervention group) and each randomly generated "even number" belongs to group 2 (patient placement in the control group)

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, patients do not know which study groups they are in. Also, the prepared medication (dexmedetomidine or remifentanil), in the same volume and appearance, is prepared and coded by a nurse colleague who is not present in the study. The anesthesiologist who also performs the procedure is not aware of the prescription drug and the grouping of patients. Patients will be evaluated by an anesthesia assistant who is not in the study group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6617913446

Approval date

2022-01-25, 1400/11/05

Ethics committee reference number

IR.MUK.REC.1400.281

Health conditions studied

1

Description of health condition studied

Bleeding during paranasal sinus surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bleeding

Timepoint

Intervals of 15 minutes during surgery

Method of measurement

The amount of bleeding during the operation will be recorded based on the surgeon's comments and according to the quality of the surgical field, as well as the amount of bleeding based on the 5-point Likert scale in 15-minute intervals during the surgery.Score 1: Uncontrolled bleeding, Score 2: Severe bleeding, surgical field is distorted immediately after suction, Score 3: Moderate bleeding, frequent suction required, vision in the surgical field is moderate,Score 4: Minor bleeding, occasional suction required, vision in the surgical field is good,Score 5: No bleeding in the surgical field, almost bloodless. The amount of blood sucked in the suction bottle will also be measured (by calculating the amount of serum used for washing and reducing it from the total volume). Blood gases will also be weighed at the end of

the operation using a heat scale.

Secondary outcomes

1

Description
Pain
Timepoint
Recovery period and every 2 hours to 6 hours after the recovery period
Method of measurement
Using the Visual Analogue Scale (VAS), which is a numerical scoring scale (zero painless to 10 highest pain), based on patient's statement.

2

Description
Vital sign (Mean arterial pressure, heart rate and SPo2)
Timepoint
Mean arterial pressure, heart rate and SPo2 will be recorded at 1 minute after intubation and then every 5 minutes to half an hour and then every 15 minutes until the end of the syrgery. It will also be measured at 15 minute intervals during the recovery period.
Method of measurement
Patient bedside monitoring device(Non invasive blood pressure, Pulse oximetry)

3

Description
Sedation - Agitation
Timepoint
At Recovery period
Method of measurement
Using the 7-point sedation-Agitation Scale (Riker)

Intervention groups

1

Description
Intervention group: After anesthesia induction in a similar plan, patients will receive dexmedetomidine (Precedex- Pfizer) at a dose of 0.2 µg / kg per hour as an infusion.
Category
Treatment - Drugs

2

Description
Intervention group: After anesthesia induction in a similar plan, patients will receive remifentanil (Ultiva - Mylan) at a dose of 0.25 µg / kg / min as an infusion.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Behzad Ahsan
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Behzad Ahsan
Position
Associate professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available