

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

Study aim

Comparison of the effect of dexmedetomidine and remifentanyl 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 remifentanyl 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, remifentanyl 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 remifentanyl 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 dexmedetomidine and remifentanyl in reducing paranasal sinus surgery bleeding: a double-blind randomized clinical trial

Public title
Comparison of the effect of dexmedetomidine and remifentanyl 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 remifentanyl), 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 surgery. 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 remifentanyl (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

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Hamdi Blvd - Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj 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?

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

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Latest degree

Specialist

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Resident

Latest degree

Medical doctor

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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