Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

The effect of medication including dexmedetomidine + remifentanil VS remifentanil on bleeding during rhinoplasty surgery

Protocol summary

Study aim

Determining the effect of prescribing a drug regimen including dexmedetomidine and remifentanil, remifentanil on the amount of bleeding during rhinoplasty.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. A table of random numbers is used for randomization.

Settings and conduct

Patients referred to the operating room of Shafa Hospital in Kerman are selected for rhinoplasty, and after induction of anesthesia and allocation of patients to two control groups (remifentanil) and intervention group (dexmedetomidine and remifentanil), hemodynamic indicators and the amount of bleeding during the operation are evaluated. In the meantime, the surgeon and the outcome assessor are blind, and only the anesthesiologist is aware of the type of drug allocation.

Participants/Inclusion and exclusion criteria

Entry requirements: Adults between 18 and 50 years of age who are candidates for rhinoplasty surgery Exit conditions: patients with physical class higher than 2؛ patients with systolic blood pressure less than 100 mmHg or heart rate less than 60 per minute؛ patients with relative or absolute prohibition of general anesthesia؛ Patients with chronic use of drugs or alcohol and special use of any type of interfering drug during anesthesia.

Intervention groups

Intervention group: receiving dexmedetomidine with a loading dose of 1.0-0.5 µg/kg and a maintenance dose (0.5-0.3 µg/kg/h) and remifentanil with a maintenance dose (0.5-0.25 mcg/kg/min IV) in the form of infusion. Control group: receiving remifentanil with a maintenance dose (0.25-0.5 mcg/kg/min IV

Main outcome variables

Bleeding volume؛ blood pressure؛ heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221202056688N1**
Registration date: **2022-12-17, 1401/09/26**
Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**
Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name
Elnaz Rahmani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3281 1111
Email address
elnaz_rahmani26@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of medication including dexmedetomidine + remifentanil VS remifentanil on bleeding during rhinoplasty surgery

Public title
Investigating the effect of the combination of a cardiovascular drug and an anesthetic drug on the amount of bleeding during nose surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Rhinoplasty surgery candidate No history of nose surgery Not suffering from chronic and severe diseases (diabetes, high blood pressure, cancer, etc.) patients with physical class higher than 2
Exclusion criteria:
Patients with systolic blood pressure less than 100 mm Hg Heart rate less than 60 per minute Patients with relative or absolute prohibition of general anesthesia Patients with chronic drug or alcohol use Specific use of any interfering drug during anesthesia
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is simple and using a table of random numbers. First, the direction of reading the numbers in the table is determined, then we move by placing our hands on a number and according to the predetermined reading direction, even numbers represent the intervention group and odd numbers represent the group. The control is used to hide sealed envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding is in such a way that only the anesthesiologist is aware of the type of drug used, and the patients, the outcome assessor, and the surgeon are unaware of the grouping and type of drugs.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences Campus, The beginning of Haft Bagh Alavi Road, Kerman,Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2022-08-02, 1401/05/11
Ethics committee reference number
IR.KMU.REC.1401.163

Health conditions studied

1

Description of health condition studied
The amount of bleeding during rhinoplasty surgery
ICD-10 code
Z42.0
ICD-10 code description
Follow-up care involving plastic surgery of head and neck

Primary outcomes

1

Description
Bleeding volume
Timepoint
After the operation is completed
Method of measurement
Calculating the amount of blood in the suction, sterile gases and the surgeon's satisfaction with the surgical field

2

Description
blood pressure
Timepoint
Before the operation, 15-30-45 minutes after the start of the intervention and the end of the operation
Method of measurement
By monitoring the patient's vital signs

3

Description
Heart rate
Timepoint
Before the operation, 15-30-45 minutes after the start of

the intervention and the end of the operation

Method of measurement

By monitoring the patient's vital signs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving dexmedetomidine with a loading dose of 1.0-0.5 µg/kg and a maintenance dose (0.5-0.3 µg/kg/h) and remifentanil with a maintenance dose (0.5-0.25 mcg/kg/min IV) in the form of infusion. will receive

Category

Treatment - Drugs

2

Description

Control group: receiving remifentanil with a maintenance dose (0.25-0.5 mcg/kg/min IV)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Elnaz Rahmani

Street address

Shafa hospital, Shafa Street, Kerman

City

Kerman

Province

Kerman

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7618751151

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpoor Afshar

Street address

Somayeh crossroad

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Province

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7619813159

Phone

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Elnaz Rahmani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
It is possible to share all data without mentioning people's names and privacy.
When the data will become available and for how long
2 months after data analysis
To whom data/document is available
Health researchers
Under which criteria data/document could be used
In order to use the results and during the written request
From where data/document is obtainable
Elnaz Rahmani- Email: elnaz_rahmani26@yahoo.com
What processes are involved for a request to access data/document
The purpose of accessing data - requesting e-mail
Comments