

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 + remifentanyl VS remifentanyl 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	<u>1</u> 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	<u>1</u> 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	<u>1</u> 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 <u>2</u> 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 <u>3</u> 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 remifentanyl 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 remifentanyl 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

Postal code

7618751151

Phone

+98 34 3211 5810

Email

kmu.nrc@gmail.com

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

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

kmu_research@yahoo.com

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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7618187568

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Jafar Salehi
Position
Assistant Professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Elnaz Rahmani
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student
Latest degree
A Level or less
Other areas of specialty/work
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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