

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 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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Havanirooz

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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  
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Assistant Professor  
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Subspecialist  
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Anesthesiology  
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## Person responsible for updating data

**Contact**  
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Kerman University of Medical Sciences  
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Elnaz Rahmani  
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student  
**Latest degree**  
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**Other areas of specialty/work**  
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elnaz\_rahmani26@yahoo.com

## 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