

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of dexmedetomidine as a adjuvant drug for local anesthesia infiltration on the rate of intraoperative bleeding and pain relief after septorhinoplasty

Protocol summary

Study aim

Evaluation the effects of dexmedetomidine, as an adjuvant to local anesthesia in rhinoplasty, on intraoperative bleeding and postoperative pain

Design

Randomized double-blind phase 3 clinical trial on 42 patients, with block randomization

Settings and conduct

This double-blind randomized clinical trial will be conducted in 2023 in Amir Alam Hospital. The randomization method in this study is the use of blocks, and patients are randomized in a ratio of 1:1 in this study. Patients will be divided into two groups receiving dexmedetomidine/not receiving dexmedetomidine.

Participants/Inclusion and exclusion criteria

The criteria for inclusion in the study are patients between 18 and 65 years of age who undergo elective septorhinoplasty surgery and do not have any history of coagulopathy or opioid drug use in the 2 months before the surgery, and patients who have a history of allergy to the study drugs, patients with heart block or chronic heart failure, high blood pressure, kidney and liver disorders, pregnancy, alcohol consumption, and diabetes will be excluded from the study.

Intervention groups

Patients who are scheduled for general anesthesia in septorhinoplasty are divided into two groups. The control group will include patients who will be given 8 ml of 2% lidocaine, 1 ml of adrenaline with a dilution of 1:100,000, and 1 ml of normal saline for local anesthesia, and in the intervention group, 8 ml 2% lidocaine, one milliliter of adrenaline with a dilution of 1:100,000, and one milliliter of dexmedetomidine will be used.

Main outcome variables

The length of time remaining in recovery, the amount of pain and agitation after surgery, the amount of bleeding after surgery, the need for opioid analgesics, the

satisfaction of patients one week after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211225053519N3**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

Mohammad Amin ShahrbaF

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 4496 0244

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of dexmedetomidine as a adjuvant drug for local anesthesia infiltration on the rate of intraoperative bleeding and pain relief after septorhinoplasty

Public title
Dexmedetomidine in rhinoplasty

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Elective Septorhinoplasty operation
Exclusion criteria:
Coagulation disorder Cardiac disorder Kidney disorder Liver disorder Consuming opioids in last two month

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the block randomization method. Blocking is usually used to balance the number of samples assigned to each study group. The size of all the blocks in this study is equal, and we will have a 4-person block size (two interventions and two controls). Random allocation software is also used as the randomization tool. The allocation concealment will be used for hiding so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences, each of the random sequences created is recorded on a card, and the cards are placed in the envelopes, respectively. To maintain a random series, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order, and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each group will have a specific code and patients, outcome assessor, and data analyzer will not be informed of the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Amir A'lam Hospital Complex

Street address

North Saadi Street

City

Tehran

Province

Tehran

Postal code

1145765111

Approval date

2022-04-17, 1401/01/28

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1401.007

Health conditions studied

1

Description of health condition studied

Pain after septorhinoplasty

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

pain

Timepoint

12 and 24 hours after the operation

Method of measurement

VAS questionnaire

2

Description

Agitation

Timepoint

12 and 24 hours after the operation

Method of measurement

RASS questionnaire

3

Description

Postoperative bleeding

Timepoint

24 hours after the operation

Method of measurement

Number of dressing in first 24 hours

4

Description

Patient satisfaction

Timepoint

During discharge

Method of measurement

ROE questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: There will be patients in whom 8 ml of 2% lidocaine, 1 ml of adrenaline with a dilution of 1:100,000, and 1 ml of normal saline will be used for local anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group: There will be patients in whom 8 ml of 2% lidocaine, 1 ml of adrenaline with 1:100,000 dilution, and 1 ml of dexmedetomidine will be used for local anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir A'lam Hospital Complex

Full name of responsible person

Nader Ali Nazemian Yazdi

Street address

North Saadi Street

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hamiralam@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nader Ali Kazemian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Pourrokn

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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

All Deidentified Individual Participant Data Set will be available after the end of the study

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers who work in an academic institute

Under which criteria data/document could be used

Data is given to the researchers just for assessment and not for interfering

From where data/document is obtainable

Through email: rezapurrokni@yahoo.com

What processes are involved for a request to access data/document

The data will given to researchers after assessing the eligibility through email

Comments