Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of dexmedetomedine as a adjuvant drug for local anesthesia infiltration on the rate of interaoperative 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)

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+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 dexmedetomedine as a adjuvant drug for local anesthesia infiltration on the rate of interaoperative 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 Pourrokni
Position
Anesthesiologist
Latest degree
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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