

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of intravenous dexmedetomidine on bleeding rate, surgeon satisfaction and hemodynamic stability in patients undergoing septorhinoplasty surgery

Protocol summary

Study aim

Investigating the effect of intravenous dexmedetomidine on bleeding rate, surgeon satisfaction and hemodynamic stability in patients undergoing septorhinoplasty surgery.

Design

This study will be a randomized double-blind phase three clinical trial with parallel groups on 74 patients referred to Motahari Jahrom Hospital who will undergo septorhinoplasty surgery under general anesthesia. Patients participating in the study will be divided into two groups using a table of random numbers.

Settings and conduct

Patients referred to Jahrom Motahari Hospital who undergo septorhinoplasty surgery with general anesthesia will be included in the study. The patients participating in the study will be divided into two groups using a table of random numbers. The person participating in the study, the researcher and the person collecting the data will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Jahrom Motahari Hospital who underwent septorhinoplasty surgery with general anesthesia and expressed their consent to participate in the study. Exclusion criteria include patients who do not have hemodynamic stability and have used anticoagulant drugs.

Intervention groups

Intervention group 1: dexmedetomidine (manufactured by Razi Company, 1 mcg/kg per ten minutes along with routine anesthesia and maintenance drugs: 6/ mcg/kg per hour). Intervention group 2: will receive placebo as the control group.

Main outcome variables

Hemodynamic symptoms: surgeon satisfaction: bleeding rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N12**

Registration date: **2023-01-18, 1401/10/28**

Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**

Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

k.navid@juma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-30, 1401/11/10

Expected recruitment end date

2023-05-26, 1402/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous dexmedetomidine on bleeding rate, surgeon satisfaction and hemodynamic stability in patients undergoing septorhinoplasty surgery

Public title

The effect of intravenous dexmedetomidine on bleeding rate, surgeon satisfaction and hemodynamic stability in patients undergoing septorhinoplasty surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Physical status of ASA class I, II Filling out the consent form to participate in the study

Exclusion criteria:

Unstable hemodynamics at the moment of entering the operating room (systolic pressure less than 90, diastole less than 60 and heart rate less than 60) Taking drugs affecting hemodynamic status Taking anticoagulants drugs

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be an easy and accessible sampling of patients undergoing septorhinoplasty surgery during the study period, but the random division of people into two groups (RANDOM ALLOCATION) will be based on a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the patient will be unaware of the type of injectable drug and only the anesthesiologist who gives the drug to the specialist will be aware of the type of injected drug. Also, injection syringes were labeled so that the type of drug is not known.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

Street address

Jahrom University of Medical Sciences, Motahari Street

City

Jahrom

Province

Fars

Postal code

7164852514

Approval date

2022-12-21, 1401/09/30

Ethics committee reference number

IR.JUMS.REC.1401.105

Health conditions studied

1

Description of health condition studied

Cosmetic Surgery

ICD-10 code

Z41.1

ICD-10 code description

Encounter for cosmetic surgery

Primary outcomes

1

Description

Hemodynamic symptoms

Timepoint

Before induction, after induction, 1 minute after induction, 5 minutes after induction, 30, 60, 90 and 120 minutes during operation, entering recovery and exiting recovery.

Method of measurement

Monitoring

2

Description

Consent of the surgeon

Timepoint

During operation every 15 minutes after the start of surgery

Method of measurement

Bezoart scale

3

Description

Bleeding

Timepoint

During surgery and at the end of the operation
Method of measurement
The amount of blood collected in suction and surgical gases

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: dexmedetomidine (manufactured by Razi Company, 1 mcg/kg per ten minutes along with routine anesthesia and maintenance drugs: 6/. mcg/kg per hour).

Category

Treatment - Drugs

2

Description

Intervention group 2: will receive placebo as the control group. The placebo includes an equal volume of normal saline injection similar to the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom Motahari Hospital

Full name of responsible person

Navid Kalani

Street address

Shahid Motahari Boulevard, Motahari Hospital, Jahrom

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7167758256

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+98 71 2536 5231

Email

Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavus Solh joo

Street address

Research Assistant, Jahrom University of Medical Sciences, Shahid Motahari Blvd, Jahrom

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solhjok@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available