

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of different doses of bolus dexmedetomidine to create controlled hypotension and the incidence of bradycardia in rhinoplasty surgery.

Protocol summary

Study aim

The effect of different doses of bolus dexmedetomidine to create controlled hypotension and the incidence of bradycardia in rhinoplasty surgery.

Design

This study is randomized clinical trial in which the number of patients is determined according to the sample size formula . The code is given and patients are randomly assigned to three treatment groups, with random code selection. The number of patients is 30 patients.

Settings and conduct

In this study, which is performed as a clinical trial in Firoozgar Hospital, patients are randomly divided into three groups after obtaining informed consent. After entering the operating room, all patients are monitored by EKG, NIBP, SPO2 and BIS, and the initial vital signs are recorded. After induction of anesthesia according to the standards, In the first group, dexmedetomidine is injected at a dose of 1 µ/kg for 10 minutes. In the second group, we inject dexmedetomidine at a dose of 9/0 µ/kg , and in the third group, we inject dexmedetomidine at a dose of 8/0 µ/kg. After 5 minutes and also at the end of 10 minutes, the patient's vital signs are recorded and the effect of the intervention on the study variables is investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA1 and ASA2 anesthesia score, The average age between 18 and 50 years. Exclusion criteria: Patient dissatisfaction with participating in the study, Not having blood pressure.

Intervention groups

In the first group, dexmedetomidine is injected at a dose of 1 µ/kg for 10 minutes. In the second group, we inject dexmedetomidine at a dose of 9/0 µ/kg , and in the third group, we inject dexmedetomidine at a dose of 8/0 µ/kg.

Main outcome variables

Moderate arterial blood pressure, Blood Pressure, Heart rate, Amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191110045388N1**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Soudabeh Djalali Motlagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1360

Email address

djalalimotlagh.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of different doses of bolus dexmedetomidine to create controlled hypotension and the incidence of bradycardia in rhinoplasty surgery.

Public title
The effect of different doses of bolus dexmedetomidine to create controlled hypotension and the incidence of bradycardia in rhinoplasty surgery.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ASA1 and ASA2 Anesthesia score. The average age between 18 and 50 years.
Exclusion criteria:
Patient dissatisfaction with participating in the study Not having blood pressure

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Balanced block randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town
City
Tehran

Province
Tehran
Postal code
1433933111
Approval date
2019-09-09, 1398/06/18
Ethics committee reference number
IR.IUMS.FMD.REC.1398.280

Health conditions studied

1

Description of health condition studied

Rhinoplasty
ICD-10 code
J34
ICD-10 code description
Other and unspecified disorders of nose and nasal sinuses

Primary outcomes

1

Description
Blood pressure
Timepoint
During Surgery
Method of measurement
Barometer

2

Description
Heart Rate
Timepoint
During Surgery
Method of measurement
Pulse Oximeter

Secondary outcomes

1

Description
Bleeding during surgery
Timepoint
During Surgery
Method of measurement
Blood volume measurement

Intervention groups

1

Description
Intervention group: In the first group, dexmedetomidine is injected at a dose of 1 µ/kg within 10 minutes after induction of anesthesia according to the required standards. Dexmedetomidine infusion (µ/kg/h 6/0-3/0) is

then used to control blood pressure during surgery. The drug is injected slowly for ten minutes once in the first stage and is used in the second stage during surgery with continuous infusion. Dexmedetomidine is manufactured by Exir Iran Pharmaceutical Company and Vial 200 micrograms per 2 ml is used.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, dexmedetomidine is injected at a dose of 9/0 µ/kg within 10 minutes after induction of anesthesia according to the required standards. Dexmedetomidine infusion (µ/kg/h 6/0-3/0) is then used to control blood pressure during surgery. The drug is injected slowly for ten minutes once in the first stage and is used in the second stage during surgery with continuous infusion. Dexmedetomidine is manufactured by Exir Iran Pharmaceutical Company and Vial 200 micrograms per 2 ml is used.

Category

Treatment - Drugs

3

Description

Intervention group: In the third group, dexmedetomidine is injected at a dose of 8/0 µ/kg within 10 minutes after induction of anesthesia according to the required standards. Dexmedetomidine infusion (µ/kg/h 6/0-3/0) is then used to control blood pressure during surgery. The drug is injected slowly for ten minutes once in the first stage and is used in the second stage during surgery with continuous infusion. Dexmedetomidine is manufactured by Exir Iran Pharmaceutical Company and Vial 200 micrograms per 2 ml is used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Soudabeh Djalali Motlagh

Street address

Unit G3, No.1 South 2nd St. Saadat Abad Ave

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8214 1360

Email

djalalimotlagh.s@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research & Technology

Street address

Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8894 6762

Email

djalalimotlagh@icloud.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Soudabeh Djalali Motlagh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Unit G3, No.1 South 2nd St. Saadat Abad Ave

City

Tehran

Province

Tehran

Postal code

1433933111

Phone
+98 21 8214 1360
Email
djalalimotlagh@icloud.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Sara Saadat
Position
Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Unit G3, No.1 South 2nd St. Saadat Abad Ave.
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 8214 1360
Email
Sara_saadat_8@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Sara Saadat
Position

Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Unit G3, No.1 South 2nd St. Saadat Abad Ave
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 8214 1360
Email
h_bf69@yahoo.com

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