Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing effect of Dexmedetomidine and Labetalol on Intraoperative blood loss and surgical field quality in Rhinoplasty: A double-Blinded Clinical Trial

Protocol summary

Study aim

Determining the effect of dexmedetomidine and labetolol on the amount of bleeding and transparency of the operation field during rhinoplasty surgery

Design

A parallel-group, single-blind, randomized, phase 3 clinical trial on 40 patients. A lottery will be used for randomization.

Settings and conduct

All people aged 17-40 years who underwent primary rhinoplasty surgery in Moradi Rafsanjan Hospital in 1401 will be included in the study. Subjects are randomly assigned to two groups a) Dexmedetomidine b) Labtolol. Systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, before induction of anesthesia and 20 minutes after induction of anesthesia (before the start of stoma) and during the stoma stage will be measured using a sphygmomanometer and pulse oximeter and will be entered in the study checklist.

Participants/Inclusion and exclusion criteria

Consent to participate in the study, age 17-40 years, being in anesthesia class I (patients with normal health who do not have any systemic problems such as cardiac, vascular, respiratory, or endocrine problems), no history of known heart disease

Intervention groups

Intervention group 1: They will receive dexmedetomidine at the rate of half to one microgram per kilogram of weight in the form of infusion at the same time as the operation begins. Intervention group 2: They will receive Labetolol in bolus injection form in the required amount (5-20 mg) intravenously during surgery.

Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, blood gas number, bleeding rate, blood weight removed from bleeding, satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150317021497N7**
Registration date: **2022-07-16, 1401/04/25**
Registration timing: **prospective**

Last update: **2022-07-16, 1401/04/25**
Update count: **0**

Registration date

2022-07-16, 1401/04/25

Registrant information

Name

Mohammadreza Mokhtaree

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34260081

Email address

mrmokhtaree@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of Dexmedetomidine and Labetalol on Intraoperative blood loss and surgical field quality in Rhinoplasty: A double-Blinded Clinical Trial

Public title

Comparing effect of Dexmedetomidine and Labetalol on Intraoperative blood loss in Rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All subjects undergoing rhinoplasty surgery since the beginning of the study for 6 months 17-40 years

Exclusion criteria:

Drug sensitivity to Dexmedetomidine and labetalol People with systolic blood pressure of 90 mmHg and lower People with a heart rate of less than 60 beats per minute upon entering the operating room

Age

From **17 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the operating room, people will be placed in study groups by lottery. Numbers 1 and 2 are written on a piece of paper and placed in sealed envelopes. The first patient will open the first envelope. If the number 1 comes out of the envelope, it is placed in the dexmedetomidine group, and of course the second person is placed in the labetalol group, and if the number 2 comes out, it is placed in the labetalol group, and the next person is placed in the dexmedetomidine group, and this process will continue until the end of the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the project partner who evaluates the hemodynamic indicators does not know about the grouping of people. Also, the data analyst does not know about the grouping of people and the data will be provided to him as a number.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7713961151

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.RUMS.REC.1401.047

Health conditions studied

1

Description of health condition studied

Systolic blood pressure

ICD-10 code

R03.0

ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

2

Description of health condition studied

Diastolic blood pressure

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Heart rate per minute

ICD-10 code

R00.8

ICD-10 code description

Other abnormalities of heart beat

4

Description of health condition studied

Mean arterial pressure

ICD-10 code

ICD-10 code description

5

Description of health condition studied

Bleeding rate

ICD-10 code

T81.2

ICD-10 code description

Accidental puncture and laceration during a procedure, not elsewhere classified

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before the start of surgery, after intubation, 20 minutes after intubation, during osteotomy, at the end of surgery, in recovery,

Method of measurement

Mercury sphygmomanometer

2

Description

Diastolic blood pressure

Timepoint

Before the start of surgery, after intubation, 20 minutes after intubation, during osteotomy, at the end of surgery, in recovery

Method of measurement

Mercury sphygmomanometer

3

Description

Heart rate

Timepoint

Before the start of surgery, after intubation, 20 minutes after intubation, during osteotomy, at the end of surgery, in recovery

Method of measurement

Pulse oximeter

4

Description

Bleeding rate

Timepoint

During osteotomy, at the end of surgery

Method of measurement

The difference in the weight of the consumed substances will be used to check the amount of bleeding. (weight of sterile gases after use + weight of suctioned liquids during surgery) - (weight of dry gases before use + amount of normal saline serum for washing the surgical site)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dexmedetomidine in the form of a vial of 200 micrograms in 2 cc has a sympatholytic effect and is used as an infusion at a dose of 1 microgram per kilogram of body weight in 100 cc of normal saline to induce controlled hypotension during anesthesia according to the patient's needs.

Category

Treatment - Drugs

2

Description

Intervention group:Labetalol vial 20 cc contains 5 mg in each cc and is an alpha and beta adrenergic blocker and causes blood pressure reduction with the mechanism of reducing peripheral vascular resistance while preventing the reflex increase of heart rate. It is a fast-acting drug that reaches its peak effect within 5 minutes. It is used in divided doses of 5 mg/cc, maximum 20 mg during anesthesia for one and a half to two hours according to the patient's needs for controlled hypotension.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Moradi hospital

Full name of responsible person

Fatemeh Jadidi

Street address

Shohada

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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7717933777
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Fatemeh Jadidi
Position
Assisstant professor
Latest degree
Specialist
Other areas of specialty/work
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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 data is potentially shareable after de-identifying

individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Commitment to the principle of fiduciary

From where data/document is obtainable

Sending an official letter to the Research Vice-Chancellor of Rafsanjan University of Medical Sciences

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

After the approval of the research vice-chancellor of Rafsanjan University of Medical Sciences, the data will be provided to the applicant.

Comments