

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effects of clonidine, morphine and promethazine as pre-medication on intraoperative bleeding and hemodynamic stability of patients during septorhinoplasty surgeries

Protocol summary

Study aim

to compare the effects of clonidine, promethazine, and morphine as premedication on intraoperative bleeding and hemodynamic stability of patients during septorhinoplasty surgeries

Design

The population of the study include all the patients who are candidate for septorhinoplasty in Birjand in 2017. A total of 60 patients who are candidate for septorhinoplasty will be selected by convenience sampling method and assigned into three groups of clonidine, promethazine and morphine (20 patients per group) using table of random numbers. The study will be conducted in two centers in the second phase of clinical trials.

Settings and conduct

The study will be performed in Valieasr and Razi hospitals of Birjand; moreover, the study is triple-blinded.

Participants/Inclusion and exclusion criteria

Major inclusion criteria consist of age from 18 to 60 years; lack of bleeding disorders such as hemophilia, thalassemia and leukemia; and lack of treatment with anti-coagulant drugs. Major exclusion criteria comprise of having systolic blood pressure above 160 mmHg and diastolic blood pressure above 90 mmHg; and unwillingness to collaborate in the study.

Intervention groups

Patients in the clonidine and promethazine groups will receive 300 milligrams of clonidine tablet and 25 milligrams of promethazine tablet, respectively, one hour before surgery. Patients in the morphine group will also receive 0.1 milligrams/kilogram body weight of morphine intramuscularly an hour before surgery. For induction of anesthesia, 100 micrograms of fentanyl and 1.5-2 milligrams/kilogram body weight propofol and 0.5 milligram/kilogram atracurium will be injected. After reaching the sufficient depth of anesthesia, intubation

will be performed using an appropriate tracheal tube. The anesthetic preservative will be propofol infusion at a dose of 100 micrograms/kilogram body weight per minute. To create controlled hypotension, infusion of remifentanyl with a dose of 0.1 microgram/kilogram body weight per minute will be used.

Main outcome variables

Systolic and diastolic blood pressures, mean arterial pressure, pulse, and saturation of red blood cells will be measured by the monitoring device (provided by Saadat Company) before induction of anesthesia, after intubation of the patient, and every 30 minutes after the onset of operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N36**

Registration date: **2018-01-31, 1396/11/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-31, 1396/11/11**

Update count: **0**

Registration date

2018-01-31, 1396/11/11

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3239 5680

Email address

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2017-06-08, 1396/03/18

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of clonidine, morphine and promethazine as pre-medication on intraoperative bleeding and hemodynamic stability of patients during septorhinoplasty surgeries

Public title

The effects of three anesthetics on the amount of intraoperative bleeding

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

aged between 18 and 60 years; no history of cardiac, pulmonary or renal diseases; no bleeding disorders such as hemophilia, thalassemia and leukemia; no severe psychosomatic disorder; no treatment with tricyclic anti-depressant drugs, monoamine oxidase enzyme inhibitors, or anti-coagulant drugs.

Exclusion criteria:

having systolic blood pressure above 160 mmHg and diastolic blood pressure above 90 mmHg; heart rate less than 50 per minute; unwillingness to collaborate in the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation is via table of random numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Firstly, the participants are blind to the pre-medication they are to receive. Although they are explained about the study design and procedure, they are not informed of

the type of medication they will receive, especially because the medications are already established as standard drugs. Moreover, on-site evaluators and statistical analysts are not aware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari St.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2017-06-07, 1396/03/17

Ethics committee reference number

IR.bums.REC.1396.65

Health conditions studied**1****Description of health condition studied**

intraoperative bleeding

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes**1****Description**

Systolic and diastolic blood pressure

Timepoint

Before induction of anesthesia, after intubation of the patient, and every 30 minutes after the start of operation

Method of measurement

Using Monitoring Device made by Saadat Company

2**Description**

Mean arterial pressure

Timepoint

Before induction of anesthesia, after intubation of the patient, and every 30 minutes after the start of operation

Method of measurement

Using Monitoring Device made by Saadat Company

3

Description

Pulse

Timepoint

Before induction of anesthesia, after intubation of the patient, and every 30 minutes after the start of operation

Method of measurement

Using Monitoring Device made by Saadat Company

4

Description

Saturation of red blood cells

Timepoint

Before induction of anesthesia, after intubation of the patient, and every 30 minutes after the start of operation

Method of measurement

Using Monitoring Device made by Saadat Company

5

Description

The amount of bleeding

Timepoint

completion of surgery

Method of measurement

Weighing the used blood-soaked gauzes and calculating the amount of blood in the suction

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (morphine): Receiving 0.1 milligram/kilogram body weight of morphine intramuscularly an hour before surgery

Category

Treatment - Drugs

2

Description

Intervention group (Promethazine): 25 milligrams of promethazine (syrup or tablet) an hour before surgery

Category

Treatment - Drugs

3

Description

Intervention group (clonidine): 300 micrograms of

clonidine tablets an hour before surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room of Valiasr Hospital

Full name of responsible person

Dr Seyed Hasan Karbasy

Street address

Taleghani St.

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Birjand

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Phone

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Email

shkarbasy@yahoo.com

2

Recruitment center

Name of recruitment center

Operating Room of Razi Hospital

Full name of responsible person

Dr Seyed Hasan Karbasy

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Ghaffari St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

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drtoobakazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

50

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

Birjand University of Medical Sciences

Full name of responsible person

Maryam Rahmanifar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Seyed Hasan Karbasy

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Bagher Roozgar

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

translation studies

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The majority of participants agreed to participate if the confidentiality of data would be guaranteed, given the type of surgery they would undergo.

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Informed Consent for Participation

When the data will become available and for how long

Unlimited

To whom data/document is available

Any researcher

Under which criteria data/document could be used

To complete and to express viewpoints

From where data/document is obtainable

the official website of Vice-chancellery of Birjand
University of Medical Sciences

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

Direct access to the website

Comments