Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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/killogram body weight of morphine intramuscularly an hour before surgery. For induction of anesthesia, 100 micrograms of fentanyl and 1.5-2 milligrams/killogram 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 remifentanil 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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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.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5000
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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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
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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Associate Professor

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Person responsible for updating data

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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