

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of Clonidine on the amount of bleeding in patients undergoing Septorhinoplasty surgery

Protocol summary

Study aim

Investigating the effect of clonidine on the amount of bleeding in patients undergoing Septorhinoplasty surgery

Design

A clinical trial with a control group, with parallel groups, double-blind, on 54 patients, Randomized by the method of Balanced Block Randomization

Settings and conduct

This study is conducted on candidates for Septorhinoplasty in Rajaee Hospital in Qazvin. After obtaining informed consent, they are randomly assigned to the experimental group or the control group. Diazepam 0.1 mg/kg orally for both groups and Clonidine 3 mg/kg orally before surgery just for the intervention group. Blood pressure is recorded before anesthesia, after intubation, at the end of surgery, and after transfer to recovery. The bleeding (the number of entirely bloody gases and blood in the suction device), Heart rate, and breathing rhythm information are entered in the form. The researcher, participant, and clinical supervisor are blinded.

Participants/Inclusion and exclusion criteria

Entry conditions: Informed consent; Candidate for Septorhinoplasty; age range from 20 to 45; Physical class above 2
Non-entry conditions: Lung disease, diabetes, coagulation disorders, ischemic heart disease; history of rhinoplasty surgery; history of smoking, alcohol, and drugs; chronic mental and physical illness; vision and hearing problems and other disabilities; Use of corticosteroids, antihistamines, painkillers, beta-blockers or calcium channel blockers; Patients with systolic blood pressure less than 100 mm Hg or heart rate less than 40 per minute; patients with the prohibition of anesthesia; Pregnancy, breastfeeding, and abortion less than 3 months

Intervention groups

Diazepam 0.1 mg per kilogram orally for both groups and Clonidine 3 micrograms per kilogram orally 90 minutes before surgery just for the intervention group is

prescribed by an anesthesiologist

Main outcome variables

Blood pressure; Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230715058778N1**

Registration date: **2023-07-23, 1402/05/01**

Registration timing: **prospective**

Last update: **2023-07-23, 1402/05/01**

Update count: **0**

Registration date

2023-07-23, 1402/05/01

Registrant information

Name

Mostafa Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Clonidine on the amount of bleeding in patients undergoing Septorhinoplasty surgery

Public title
Effect of Clonidine on the bleeding of Septorhinoplasty patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for Septorhinoplasty Age range 20-45 Physical class above 2 Willingness to participate in research with informed consent after giving necessary and sufficient explanations about the study
Exclusion criteria:
Having any lung disease History of Rhinoplasty surgery History of smoking, alcohol and drugs Chronic mental and physical illness (Schizophrenia, Diabetes, etc.) Vision and hearing problems and other disabilities Long-term use of Corticosteroids, antihistamines, narcotics and painkillers Having diabetes Coagulation disorders Ischemic heart disease History of taking beta blockers or calcium channel blockers patients with systolic blood pressure less than 100 mmHg or heart rate less than 40per minute patients with relative or absolute prohibition of general anesthesia Pregnancy, breast feeding and abortions less than 3 months

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of random allocation in this study is Balanced Block Randomization. 6 blocks AABB- ABAB_ ABBA- BBAA- BABA_ BAAB are numbered based on 1 to 6 and numbers 1 to 6 are selected from the table of random numbers and placed together. Then they are replaced with numbered blocks

Blinding (investigator's opinion)
Double blinded

Blinding description
The evaluator gives the pill in an unspecified package to the patient randomly before induction of anesthesia. The surgeon and the clinical caregiver are blinded, and the patient does not know what drug he used and whether this drug was one of the study drugs or part of the

hospital's routine.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Research and Technology deputy, 1st Branch, Maudet Alley, Shahid Beheshti Blvd, Qazvin
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Qazvin
Province
Qazvin
Postal code
3415613911

Approval date
2023-07-14, 1402/04/23

Ethics committee reference number
IR.QUMS.REC.1402.099

Health conditions studied

1

Description of health condition studied
Bleeding during Septorhinoplasty surgery

ICD-10 code
Y52.5

ICD-10 code description
Other antihypertensive drugs, not elsewhere classified

Primary outcomes

1

Description
The effect of Clonidine on blood pressure during Septorhinoplasty

Timepoint
Systolic and diastolic blood pressure are measured before induction of anesthesia, after intubation of the patient, at the end of surgery and after transfer to recovery.

Method of measurement
Blood pressure measurement is done by monitoring device and recorded by evaluator

2

Description

The effect of clonidine on the amount of bleeding during Septorhinoplasty

Timepoint

After surgery

Method of measurement

The amount of blood in the suction device and the number of completely blood gases. Before the operation, a strong pharyngeal peg is inserted by the surgeon, and at the end of the operation, after the peg is removed, the blood in the nasopharynx is suctioned and added to the amount of bleeding.

Secondary outcomes

1

Description

Effect of Clonidine on heart rate

Timepoint

Before induction of anesthesia, after patient intubation, at the end of surgery and after transfer to recovery

Method of measurement

Monitoring device

2

Description

breathing rhythm

Timepoint

Before induction of anesthesia, after patient intubation, at the end of surgery and after transfer to recovery

Method of measurement

Monitoring device

Intervention groups

1

Description

Intervention group: Diazepam 0.1 mg per kilogram orally and Clonidine 3 micrograms per kilogram orally 90 minutes before surgery are prescribed by the anesthesiologist in a room with a temperature of 25 degrees Celsius.

Category

Treatment - Drugs

2

Description

Control group: Diazepam 0.1 mg per kilogram is administered orally by an anesthesiologist in a room with a temperature of 25 degrees Celsius.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Mostafa Ghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mahidi Mirhashemi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

1

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

Qazvin University of Medical Sciences

Full name of responsible person

Mostafa Ghasemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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

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 can be shared after individuals are de-identified

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any kind of analysis on the delivered data is allowed

From where data/document is obtainable

Refer to Dr.Mostafa Ghasemi s Email
Dr.mostafaghasemi@yahoo.com

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

After publishing the article, the applicant can send a clear request to the author to access the data by sending an email. So, after reviewing the request within 2 weeks, access to data and information is allowed.

Comments