

# 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)

##### Phone

+98 21 3379 0620

##### Email address

dr.mostafaghasemi@yahoo.com

##### 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  
**City**  
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

#### **Street address**

22 Bahman Blvd, Tavon Square, Elahiye Quay, Minodar Town

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#### **Postal code**

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#### **Email**

Clinical\_research@qums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Qazvin University of Medical Sciences

#### **Full name of responsible person**

Seyyed Mahidi Mirhashemi

#### **Street address**

Mavaddat Alley ,Research and Technology deputy, Shahid Beheshti Blvd, Qazvin

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#### **Email**

researchdpt@qums.ac.ir

### **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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## Person responsible for scientific inquiries

### Contact

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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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**