Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of clonidine and magnesium sulfate on bleeding control in septorhinoplasty surgery

Protocol summary

Study aim
Comparison of the effect of clonidine and magnesium sulfate on bleeding control in septorhinoplasty surgery.

Design
Clinical trial with 2 interventional group, Block randomization, 43 subjects in each group, with parallel groups, double blind

Settings and conduct
This study will be performed in 5th Azar hospital in Gorgan. Patients will be placed in one of 2 intervention groups. The sampling method is simple randomization. Letter A as for to clonidine group with a dose of µg/kg 5 and letter B as for to magnesium sulfate group with a dose of 50 mg/kg. This process will continue until 43 people are selected for each group. Also, from the time of entering the operating room and throughout the surgery, the patient's hemodynamics will be recorded and the total amount of bleeding at the end of the operation will be calculated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with ASA I are candidates for septorhinoplasty؛Exclusion criteria: Patients with known neuromuscular disease، History of neuropathy، Obese patients BMI> 35، History of coagulation disorders، Renewed rhinoplasty، History of calcium channel blockers، A history of drug use NSAID, antiepileptic, TCA، History of underlying diseases such as asthma, migraine، History of allergies to drugs used for induction

Intervention groups
first Intervention group: The clonidine is given to the patient by the head nurse one hour before the start of surgery in the ward؛ second Intervention group: 50 mg/kg sulfate magnesium In normal saline it reaches a volume of 50 cc.

Main outcome variables
The amount of bleeding volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170413033408N4**
Registration date: **2020-10-14, 1399/07/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-14, 1399/07/23**
Update count: **0**

Registration date
2020-10-14, 1399/07/23

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 17 3254 9891
Email address
dr.mojaveraghili@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of clonidine and magnesium sulfate

on bleeding control in septorhinoplasty surgery

Public title
effect of clonidine and magnesium sulfate on rhinoplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with ASA I are candidates for septorhinoplasty
Exclusion criteria:
Patients with known neuromuscular disease History of neuropathy Obese patients BMI> 35 History of coagulation disorders Renewed rhinoplasty History of calcium channel blockers A history of drug use NSAID, antiepileptic, TCA History of underlying diseases such as asthma, migraine History of allergies to drugs used for induction and anesthesia management used in these patients
Age
From **15 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the participants who have the inclusion criteria to the study، How to allocate patients to one of the two drug groups will be done based on block randomization method. So that a random sequence of letters A and B is created by 43 double blocks and It will be provided to one of the members of the research team، This member will not interfere in the selection of samples.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are BLIND to their study group after obtaining their consent. The principal investigator will also not know the type of group therapy. All anesthesia procedures will be performed by an anesthesiologist who is unaware of the treatment groups under the same conditions and medication regimen for the participants, and information will be collected by an anesthesiologist unaware of the treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran
City
Gorgan
Province
Golestan
Postal code
49341-74515
Approval date
2020-02-23, 1398/12/04
Ethics committee reference number
IR.GOUMS.REC.1399.177

Health conditions studied

1

Description of health condition studied
Candidates for septorhinoplasty surgery
ICD-10 code
Z41.1
ICD-10 code description
Other plastic surgery for unacceptable cosmetic appearance

Primary outcomes

1

Description
The amount of bleeding volume
Timepoint
The measure of bleeding volume will be calculated from the beginning of the surgery until the end of the surgery.
Method of measurement
patient bleeding is noted by collecting the blood in the bottle of suction, which is calibrated every 10 cc, and the calculation blood volume of gas in the patient’s throat.

2

Description
hemodynamic changes
Timepoint
The patient's hemodynamic monitoring will be performed from the time of entering the operating room until the end of the operation.
Method of measurement
Hemodynamic criteria (heart rate, systolic, diastolic, and mean arterial blood pressure (MABP), arterial oxygen saturation) of the patient will be measured by Saadat monitoring.

Secondary outcomes

empty

Intervention groups

1

Description
first Intervention group: The clonidine is given to the patient by the head nurse one hour before the start of surgery in the ward.
Category
Treatment - Drugs

2

Description
second Intervention group: 50 mg/kg sulfate magnesium In normal saline it reaches a volume of 50 cc.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan 5 Azar Educational and Medical Center
Full name of responsible person
Seyed babak mojaver aghili
Street address
Gorgan-Sari road 4th kilometers, Golestan University of Medical Sciences, School of Medicine - Anesthesiology Department
City
Gorgan
Province
Golestan
Postal code
4917761551
Phone
+98 17 3223 8363
Email
drbabaka35@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Reza Honarvar
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran
City
Gorgan
Province
Golestan
Postal code
49341-74515
Phone
+98 17 3253 8011
Email
honarvar@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Seyed Babak Mojaver Aghili
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran
City
Gorgan
Province
Golestan
Postal code
49341-74515
Phone
+98 17 3253 8011
Email
drbabaka35@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person

Seyed Babak Mojaver Aghili
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran
City
Gorgan
Province
Golestan
Postal code
49341-74515
Phone
+98 17 3253 8011
Email
drbabaka35@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Seyed Babak Mojaver Aghili
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran
City
Gorgan
Province
Golestan
Postal code
49341-74515
Phone
+98 17 3253 8011
Email
drbabaka35@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the main outcome
When the data will become available and for how long
Since 2020
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
No manipulation, mentioning the data reference
From where data/document is obtainable
Seyed Babak Mojaver Aghili, drbabaka35@gmail.com, Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology, Gorgan, Golestan, Iran.
What processes are involved for a request to access data/document
sending an email, complete the personal and professional characteristics with documentation
Comments