

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 $\mu\text{g}/\text{kg}$ 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

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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

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Phone

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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

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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

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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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Latest degree

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Email

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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