Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of intravenous magnesium sulfate and labetalol on intraoperative bleeding and postoperative edema and ecchymosis in rhinoplasty

Protocol summary

Study aim

Comparison of the effect of intravenous magnesium sulfate and labetalol on intraoperative bleeding and lack of banana hockey after rhinoplasty

Design

A double-blind clinical trial, in two groups of magnesium sulfate and labetalol, with parallel, randomized, phase 3 groups on 60 patients, PASS11 software is used for randomization.

Settings and conduct

The project site is Amir Al-Momenin Hospital in Rasht. Blindness is such that only the anesthesiologist is aware of the type of drug being used and all patients, researchers and surgeons are unaware of the patient's exposure. In the sulfate group, 30 to 50 mg / kg intravenous magnesium sulfate is given before induction of anesthesia, and 10 to 20 mg / kg intravenous magnesium sulfate is infused during surgery. In the labetalol group, the infusion of labetalol is 1 mg / min intraoperatively (limit less than 300 mg).

Participants/Inclusion and exclusion criteria

The statistical population includes people who undergo rhinoplasty surgery in Amir Al-Momenin Hospital in Rasht at a specific time. Inclusion criteria include age over 18 and consent to participate in the study

Intervention groups

The aim of this clinical trial was to compare the effect of intravenous magnesium sulfate and labetalol on intraoperative bleeding, edema and ecchymosis after rhinoplasty in two groups of magnesium sulfate and labetalol.

Main outcome variables

Bleeding during surgery; Edema and ecchymosis after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211108053010N1**
Registration date: **2022-05-28, 1401/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-28, 1401/03/07**
Update count: **0**

Registration date

2022-05-28, 1401/03/07

Registrant information

Name

Shaghayegh Rezaeekia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3346 9321

Email address

shaghayeghrezaeekia1375@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of intravenous magnesium sulfate and labetalol on intraoperative bleeding and postoperative edema and ecchymosis in rhinoplasty

Public title
Comparison of the effect of intravenous magnesium sulfate and labetalol on intraoperative bleeding and postoperative edema and ecchymosis in rhinoplasty

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
over 18 years old consent to participate in the study

Exclusion criteria:
history of hypertension peripheral vascular problems renal, hepatic or hematologic disorders pregnancy obesity diabetic neuropathy uncontrollable hypertension previous treatment with any antihypertensive drug, opioid or anticoagulant magnesium supplementation consumption Chronic drug drug use such as aspirin allergy to magnesium sulfate, drugs or other drugs under study

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are randomly divided into two groups using PASS11 software. Random allocation was performed by Efron method with one thousand repetitions and due to this method, an equal number of samples in each block are placed in two groups of magnesium sulfate and labetalol. In randomization, equal chances are provided for all samples to be in one of the two groups. The researcher does not interfere in determining the group for the samples.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blindness is such that only the anesthesiologist is aware of the type of drug being used and all patients, researchers and surgeons are unaware of the patient's reception.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Farahabad Street

City
sari

Province
Mazandaran

Postal code
4815733971

Approval date
2022-05-15, 1401/02/25

Ethics committee reference number
IR.MAZUMS..REC.1401.13695

Health conditions studied

1

Description of health condition studied
Bleeding during rhinoplasty

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Edema and ecchymosis after rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The amount of bleeding during the operation

Timepoint
End of operation

Method of measurement
Measure lost blood by examining gases and suction

2

Description
The rate of ecchymosis

Timepoint
24 hours and one week after surgery

Method of measurement
Standard tool for scoring degree of ecchymosis

3

Description
The amount of edema
Timepoint
24 hours and one week after surgery
Method of measurement
Standard tool for scoring degree of edema

Secondary outcomes

1

Description
Sore throat
Timepoint
Postoperatively and 24 hours after surgery
Method of measurement
4 degree scale of sore throat

2

Description
headache
Timepoint
24 hours after surgery
Method of measurement
Question

3

Description
Orthostatic hypotension
Timepoint
24 hours after surgery
Method of measurement
Barometer

4

Description
Respiratory depression
Timepoint
24 hours after surgery
Method of measurement
See the number of breaths per minute

5

Description
surgeon consent
Timepoint
After surgery
Method of measurement
Boezaart criteria

Intervention groups

1

Description
Intervention group: In the sulfate group, 30 to 50 mg / kg intravenous magnesium sulfate is given before induction of anesthesia, and 10 to 20 mg / kg intravenous magnesium sulfate is infused during surgery. Magnesium sulfate is prepared from Shahid Ghazi Pharmaceutical Company, Tabriz, Iran.
Category
Prevention

2

Description
Intervention group: In the labetalol group, the infusion of labetalol is 1 mg / min intraoperatively (limit less than 300 mg). Labetalol is produced by Restagen Daru Pharmaceutical Company, Tehran, Iran.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-momenin Hospital, rasht
Full name of responsible person
Hooshang akbari
Street address
17 Shahrivar Street
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4139637459
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences
Street address
Moalem Square
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4815733971
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Email
pajoheshi@mazums.ac.ir
Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran University of Medical Sciences

Proportion provided by this source
70

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
Mazandaran University of Medical Sciences

Full name of responsible person
Shaghayegh Rezaeekia

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Others

Street address
Mehr Town, 103 Mehr Alley, Block 42, Unit 11

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Rasht

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hooshang Akbari

Position
Assistant professor

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Anesthesiology

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Person responsible for updating data

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Full name of responsible person
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Position
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Latest degree
Bachelor

Other areas of specialty/work
Others

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
It is possible to share all data by not mentioning the names of people and protecting the privacy of people.

When the data will become available and for how

long

After publishing the related article

To whom data/document is available

Researchers of university centers

Under which criteria data/document could be used

After obtaining a license and approval from the Vice Chancellor for Research of Mazandaran University of Medical Sciences

From where data/document is obtainable

Refer to Shaghayegh Rezaee Kia project manager with email address: shaghayeghrezaeekia1375@gmail.com and Phone number: 09386589690

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

After obtaining a license and approval from the Vice Chancellor for Research of Mazandaran University of Medical Sciences and referring to the project manager

Comments