Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Safety and efficacy of magnesium sulfate as an adjuvant to peribulbar block for glaucoma surgery in morbidly obese patients: A randomized clinical trial

Protocol summary

Study aim

Evaluation of the efficacy and safety of adding two different doses of magnesium sulfate (75 mg & 100 mg) as an adjuvant to peribulbar block in reducing the intraocular pressure in morbidly obese patients undergoing glaucoma surgery.

Design

Parallel group randomized clinical trial with 1:1 allocation ratio.

Settings and conduct

Research Institute of Ophthalmology, Giza, Egypt.

Participants/Inclusion and exclusion criteria

We will include adult (18-70 years-old), morbidly obese (body mass index of 30-55 kg/m2), male or female patients, indicated for glaucoma surgery who are American Society of Anesthesiologists physical status I, II or III and have an axial length of 20-28 mm. We will exclude patients with coagulopathy or on anticoagulant drugs or having allergy to any of the used drugs. Also, we will exclude patients with conditions preventing them from lying flat or staying still during the operation as skeletal problems or orthopneic patients or those with uncontrolled tremors (as Parkinsonism).

Intervention groups

The trial has two groups. The first group will be given peribulbar anesthesia with a local anesthetic mixture composed of 4 ml of lidocaine 2%, 4 ml of bupivacaine 0.5%, and hyaluronidase (at a concentration of 10 IU/ml of lidocaine) to which 75 mg of magnesium sulfate will be added. The second group will receive the same doses and concentrations of lidocaine, bupivacaine, and hyaluronidase to which 100 mg of magnesium sulfate will be added.

Main outcome variables

The primary outcome variables include the onset of globe akinesia, onset of lid akinesia, and intraocular pressure. The secondary outcomes include the duration of analgesia, duration of motor block, patient satisfaction, surgeon satisfaction, and vital data (heart rate, oxygen saturation, non-invasive blood pressure).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210118050069N1**
Registration date: **2021-01-27, 1399/11/08**
Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**
Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Norhan Sherif

Name of organization / entity

Research Institute of Ophthalmology

Country

Egypt

Phone

+20 2 35718304

Email address

anesth.sherif@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-01, 1399/11/13

Expected recruitment end date

2021-03-01, 1399/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of magnesium sulfate as an adjuvant to peribulbar block for glaucoma surgery in morbidly obese patients: A randomized clinical trial

Public title

Magnesium sulfate as an adjuvant to peribulbar block for glaucoma surgery in morbidly obese patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Glaucoma surgery patients ASA physical status I, II, or III Aged from 18 to 70 years Axial length 20-28 mm Body mass index 30-55 kg/m2

Exclusion criteria:

Coagulopathy or use of anticoagulant drugs Previous allergy or adverse reaction to the used drugs Patients with conditions preventing them from lying flat or staying still during operation as skeletal problems, orthopneic patients, or those with uncontrolled tremors (as Parkinsonism)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

We used the sealed, opaque sequentially numbered envelopes method for randomization and allocation concealment of patients included in this trial. We used 46 identical, opaque, letter-sized envelopes. We used rolls of household aluminum cooking foil that we cut into 46 sheets (of the same width as and twice the height of the envelope). We prepared 46 envelope-sized sheets of white paper and 46 envelope-sized sheets of single sided carbon paper. We wrote “Treatment A” on 23 paper sheets and “Treatment B” on another 23 sheets. To prepare 23 “Treatment A” envelops, we selected one envelope-sized sheet of of Treatment A and placed one sheet of carbon paper on top of the Treatment A allocation paper with the carbon side facing the paper, then we put both papers inside a foil wrapper. Then, the completed insert was placed into a blank envelope with the carbon paper closest to the front of the envelope. Finally, the envelop was sealed and we signed across the seal. We completed all the 23 “Treatment A” envelops the same way. We prepared 23 “Treatment B” envelops the same way as “Treatment A” envelops. The two sets of envelops were combined and shuffled thoroughly. Using a pen we marked a number on the front of each envelope sequentially from 1 to 46. Logically, the carbon paper inside the envelope will transfer this number to the allocation paper inside. Finally, we placed these envelopes into a plastic container, in numerical order, ready for use.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All of the following will be blinded to the type of intervention: Participants, Care providers (carrying out the peribulbar block), Health professionals (assessing the participants' outcomes), and Data analyzers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Committee of the Research Institute of Ophthalmology

Street address

2 El Ahram Street

City

Giza

Postal code

12557

Approval date

2020-11-08, 1399/08/18

Ethics committee reference number

8-11-2020

Health conditions studied

1

Description of health condition studied

Peribulbar block in adult, morbidly obese patients undergoing glaucoma surgery.

ICD-10 code

H40

ICD-10 code description

Glaucoma

Primary outcomes

1

Description
The onset of globe akinesia.
Timepoint
At 1, 3, and 5 min after the block.
Method of measurement
The 3-point scale.

2

Description
The onset of lid akinesia.
Timepoint
At 1, 3, and 5 min after the block.
Method of measurement
The 3-point scale.

3

Description
The intraocular pressure.
Timepoint
At baseline, 1, 3, and 5 minutes after local anesthesia.
Method of measurement
Schiotz tonometer.

Secondary outcomes

1

Description
The duration of analgesia.
Timepoint
At 1, 2, and 4 h postoperative.
Method of measurement
The Visual Analogue Scale.

2

Description
The duration of motor block.
Timepoint
At 1, 2, and 4 h postoperative.
Method of measurement
Clinical assessment of regaining full movement.

3

Description
Patient satisfaction.
Timepoint
Immediately after the block.
Method of measurement
Asking the patient.

4

Description
Surgeon satisfaction.
Timepoint
Immediately after the block.
Method of measurement
Asking the surgeon.

5

Description
The vital data (heart rate, oxygen saturation, and non-invasive blood pressure).
Timepoint
Every 5 minutes during the operation.
Method of measurement
Electronic vital signs monitor.

Intervention groups

1

Description
Intervention group 1 (MS-75): This group will be given peribulbar anesthesia with a local anesthetic mixture composed of 4 ml of lidocaine 2% (Sunny Pharmaceutical, Egypt), 4 ml of bupivacaine 0.5% (Sunny Pharmaceutical, Egypt), and 1 ml of hyaluronidase (Shreya Life Sciences Pvt. Ltd., India) (at a concentration of 10 IU/ml of lidocaine) to which 75 mg of magnesium sulfate (EIPICO Pharmaceutical, Egypt) will be added.
Category
Other

2

Description
Intervention group 2 (MS-100): This group will be given peribulbar anesthesia with a local anesthetic mixture composed of 4 ml of lidocaine 2% (Sunny Pharmaceutical, Egypt), 4 ml of bupivacaine 0.5% (Sunny Pharmaceutical, Egypt), and 1 ml of hyaluronidase (Shreya Life Sciences Pvt. Ltd., India) (at a concentration of 10 IU/ml of lidocaine) to which 100 mg of magnesium sulfate (EIPICO Pharmaceutical, Egypt) will be added.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Institute of Ophthalmology
Full name of responsible person
Dr. Norhan Sherif
Street address
2 El Ahram Street
City
Giza
Postal code
12557
Phone
+20 2 35718304
Email
anesth.sherif@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute of Ophthalmology
Full name of responsible person
Dr. Norhan Sherif
Street address
2 El Ahram Street
City
Giza
Postal code
12557
Phone
+20 2 35718304
Email
anesth.sherif@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Self-funded
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Research Institute of Ophthalmology
Full name of responsible person
Dr. Norhan Sherif
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
2 El Ahram Street
City
Giza
Province
Cairo
Postal code
12557
Phone
+20 2 35718304
Email
anesth.sherif@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Research Institute of Ophthalmology
Full name of responsible person
Dr. Norhan Sherif
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
2 El Ahram Street
City
Giza
Province
Cairo
Postal code
12557
Phone
+20 2 35718304
Email
anesth.sherif@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Research Institute of Ophthalmology
Full name of responsible person
Dr. Norhan Sherif
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
2 El Ahram Street
City
Giza
Province
Cairo
Postal code
12557
Phone
+20 2 35718304
Email
anesth.sherif@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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Magnesium sulfate in peribulbar block for glaucoma surgery IPD set (all collected deidentified IPD).

When the data will become available and for how long

Beginning 6 months and ending 24 months following article publication.

To whom data/document is available

Researchers from academic institutions whose proposal for the use of data has been approved by an independent review committee identified for this purpose.

Under which criteria data/document could be used

For IPD meta-analysis.

From where data/document is obtainable

From the principal investigator (A proposal for the use of data to be submitted to the principal investigator).

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

A proposal for the use of data to be submitted to the principal investigator, then evaluated by an independent review committee identified for this purpose.

Comments