# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 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**