Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Ketamine versus magnesium sulphate as an adjuvant to local anesthetics in the peribulbar block for posterior segment surgeries: A randomized controlled study

Protocol summary

Study aim

To evaluate the effects of ketamine and magnesium sulphate as adjuvants to local anesthetic mixtures on the onset, duration, and quality of peribulbar block in patients scheduled for posterior segment surgeries.

Design

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

Settings and conduct

Research Institute of Ophthalmology, Giza, Egypt.

Participants/Inclusion and exclusion criteria

We included adult (45-65 years-old), male and female patients, scheduled for posterior segment operations who were American Society of Anesthesiologists physical status I or II and had an axial length < 25 mm. We excluded patients with coagulation abnormalities, impaired mental status, allergy to any of the study medications, and those having problems that interfere with surgeon patient communication and cooperation as deafness. In addition, patients with severe cardiac disease, chronic obstructive lung disease, history of sleep apnea, advanced liver or kidney disease, and history of chronic use of sedatives, narcotics, alcohol or drug abuse were excluded.

Intervention groups

The current trial has three groups. The first was given peribulbar anesthesia with a local anesthetic mixture composed of lidocaine 2% (4.5 ml), plain bupivacaine 0.5% (4.5 ml), 1 ml of normal saline, and hyaluronidase (13.5 IU per ml of the mixture). The second received the same anesthetic mixture plus 25 mg of ketamine added to 1 ml of normal saline. The third received the same anesthetic mixture plus 50 mg of magnesium sulphate added to 1 ml of normal saline.

Main outcome variables

Outcome variables included the onset and duration of globe akinesia, duration of lid akinesia, onset of sensory block, time to start surgery, total analgesic time, intraocular pressure, and patient and surgeon satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210220050419N1**
Registration date: **2021-02-27, 1399/12/09**
Registration timing: **retrospective**

Last update: **2021-02-27, 1399/12/09**
Update count: **0**

Registration date

2021-02-27, 1399/12/09

Registrant information

Name

Eslam Saleh

Name of organization / entity

Research Institute of Ophthalmology

Country

Egypt

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-01, 1398/01/12

Expected recruitment end date

2020-04-01, 1399/01/13

Actual recruitment start date

2019-04-12, 1398/01/23

Actual recruitment end date

2020-07-31, 1399/05/10

Trial completion date

2020-07-31, 1399/05/10

Scientific title

Ketamine versus magnesium sulphate as an adjuvant to local anesthetics in the peribulbar block for posterior segment surgeries: A randomized controlled study

Public title

Ketamine versus magnesium sulphate as an adjuvant to local anesthetics in the peribulbar block for posterior segment surgeries

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Posterior segment operations American Society of Anesthesiologist (ASA) physical status I or II Age: 45-65 years Axial length: < 25 mm

Exclusion criteria:

Coagulation abnormalities Impaired mental status Allergy to any of the study medications Problems that interfere with surgeon patient communication and cooperation as deafness Severe cardiac disease, chronic obstructive lung disease, history of sleep apnea, advanced liver or kidney disease History of chronic use of sedatives, narcotics, alcohol or drug abuse Patient refusal

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **126**

Actual sample size reached: **126**

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 126 identical, opaque, letter-sized envelopes lined with sheets of household aluminum cooking foil to ensure opacity. We prepared 126 envelope-sized sheets of white paper and 126 envelope-sized sheets of single sided carbon paper. We wrote “Treatment A” on 42 paper sheets, “Treatment B” on another 42 sheets, and “Treatment C” on the last 42 sheets. To prepare 42 “Treatment A” envelops, we selected one envelope-sized sheet 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 inserted both into a blank envelope with the carbon paper closest to the front of the envelope. Finally, we sealed the envelop and signed across the seal. We completed all the 42 “Treatment A” envelops the same way. We prepared 42 “Treatment B” as well as 42 “Treatment C” envelops similar to “Treatment A” envelops. The three 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 126 so the carbon paper inside the envelope transfer this number to the allocation paper inside. Finally, we placed these envelopes into a large plastic container, in numerical order, ready for use.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study participants and care providers (carrying out the peribulbar block and assessing the participants' outcomes) were blinded to the type of intervention.

Placebo

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

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Giza

Postal code

12557

Approval date

2019-04-11, 1398/01/22

Ethics committee reference number

11-4-2019

Health conditions studied

1

Description of health condition studied

Peribulbar block in adult patients undergoing posterior segment surgeries.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The onset of sensory block.

Timepoint
At 1, 2, 3, 4, and 5 min after the block.
Method of measurement
A small piece of cotton wool.

2

Description
The onset of globe akinesia.
Timepoint
At 1, 3, 5, 7, and 10 min after the block.
Method of measurement
The 3-point scale.

3

Description
The Duration of lid akinesia.
Timepoint
At 1, 2, 3, 4, and 5 h postoperative.
Method of measurement
Clinical assessment of regaining full movement.

4

Description
The duration of globe akinesia.
Timepoint
At 1, 2, 3, 4, and 5 h postoperative.
Method of measurement
Clinical assessment of regaining full movement.

Secondary outcomes

1

Description
Patient satisfaction.
Timepoint
After recovery.
Method of measurement
7-point Likert-like verbal rating scale.

2

Description
Surgeon satisfaction.
Timepoint
At the end of surgery.
Method of measurement
The 7-point Likert-like verbal rating scale.

3

Description
The duration of analgesia.
Timepoint
At 1, 2, 3, 4, and 5 h postoperative.
Method of measurement
The 10-point Visual Analog Scale

4

Description
The intraocular pressure.
Timepoint
At baseline and 10 minutes after injection of the local anesthetics.
Method of measurement
Schiotz tonometer

5

Description
Time to start surgery.
Timepoint
At 1, 3, 5, 7, and 10 min after the block.
Method of measurement
Corneal anesthesia together with an ocular movement score ≤1 in each direction and an eyelid akinesia score of 0 (total score <5).

Intervention groups

1

Description
Control group (GC) received peribulbar anesthesia with a local anesthetic mixture composed of lidocaine 2% (4.5 ml), plain bupivacaine 0.5% (4.5 ml), 1 ml of normal saline, and hyaluronidase (13.5 IU per ml of the local anesthetic mixture).
Category
Other

2

Description
Intervention group (GK) received a local anesthetic mixture composed of lidocaine 2% (4.5 ml), plain bupivacaine 0.5% (4.5 ml), 25 mg of ketamine in 1 ml of normal saline, and hyaluronidase (13.5 IU per ml of the local anesthetic mixture).
Category
Other

3

Description
Intervention group (GM) received a local anesthetic mixture composed of lidocaine 2% (4.5 ml), plain bupivacaine 0.5% (4.5 ml), 50 mg of magnesium sulphate in 1 ml of normal saline, and hyaluronidase (13.5 IU per ml of the local anesthetic mixture).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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

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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
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
Ketamine and magnesium sulphate in peribulbar block for posterior segment surgeries 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-analyses.
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
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