

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of adding different doses of neostigmine in peribulbar block for intraoperative anesthesia and post-operative analgesia in cataract surgery

Protocol summary

Study aim

Evaluation of the efficacy and safety of adding two different doses of neostigmine to the local anesthetic lidocaine in peribulbar anesthesia for cataract surgery.

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 will include adult (30-70 years-old) male or female patients, indicated for cataract surgery who are ASA I, II or III. We will exclude patients with any of the following conditions: coagulopathy or on anticoagulant drugs, infection at the site of the surgery, posterior staphyloma, allergy to any of the used drugs, and bronchial asthma or bradyarrhythmia.

Intervention groups

The trial has three groups. Control group (Group C) includes 20 patients. Each will receive 9 ml of lidocaine 2% (containing 1 ml = 10 unit of hyaluronidase) + 1 ml of saline. Intervention group 1 (Group N1) includes 20 patients. Each will receive 9 ml of lidocaine 2% (containing 1 ml = 10 unit of hyaluronidase) + 0.5 mg of neostigmine. Intervention group 2 (Group N2) includes 20 patients. Each will receive 9 ml of lidocaine 2% (containing 1 ml = 10 unit of hyaluronidase) + 0.25 mg of neostigmine.

Main outcome variables

The primary outcome variables include hemodynamics (heart rate, blood pressure, oxygen saturation) and the onset of motor and sensory blocks. The secondary outcomes include the duration of the block, patient's and surgeon's satisfaction, postoperative pain using VAS, and the first dose of analgesic required.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210106049952N1**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **prospective**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Iman Sobhy

Name of organization / entity

Research Institute of Ophthalmology

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Egypt

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iman.sobhy333@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-15, 1399/10/26

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

The effect of adding different doses of neostigmine in peribulbar block for intraoperative anesthesia and post-operative analgesia in cataract surgery

Public title

The effect of adding different doses of neostigmine in peribulbar block for cataract surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Cataract surgery patients (male or female) aged from 30 to 70 years ASA physical status I, II, or III

Exclusion criteria:

Coagulopathy or use of anticoagulant drugs Infection at the site of surgery Posterior staphyloma Previous allergy or adverse reaction to the used drugs Bronchial asthma or bradyarrhythmia

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

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 60 identical, opaque, letter-sized envelopes. We used rolls of household aluminum cooking foil that we cut into 60 sheets (of the same width as and twice the height of the envelope). We prepared 60 envelope-sized sheets of white paper and 60 envelope-sized sheets of single sided carbon paper. We wrote "Treatment A" on 20 paper sheets, "Treatment B" on another 20 sheets, and "Treatment C" on the last 20 sheet. To prepare 20 "Treatment A" envelopes, 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 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 envelope was sealed and we signed across the seal. We completed all the 20 "Treatment A" envelopes the same way. We prepared 20 "Treatment B" envelopes and 20 "Treatment C" envelopes the same way as "Treatment A" envelopes. The three sets of envelopes were combined and we shuffled them thoroughly. Then, using a pen we marked a number on the front of each envelope sequentially

from 1 to 60. 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

Participants, care providers carrying out the peribulbar block, and those assessing the participants' outcomes will be 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

City

Giza

Postal code

12557

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

1-12-2020

Health conditions studied

1

Description of health condition studied

Peribulbar block in adult patients undergoing cataract surgery.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemodynamics (heart rate, blood pressure, and oxygen saturation)

Timepoint

Baseline, immediately after the block, and one hour after the block

Method of measurement

Electronic vital signs monitor

2

Description

Onset of sensory block

Timepoint

Every 5 seconds after the block

Method of measurement

Clinical assessment

3

Description

Onset of motor block

Timepoint

Every 5 seconds after the block

Method of measurement

Clinical assessment

Secondary outcomes

1

Description

Duration of the block

Timepoint

Every 10 minutes following the block

Method of measurement

Clinical assessment

2

Description

Postoperative pain

Timepoint

Immediately after the block

Method of measurement

Visual analog scale

3

Description

Surgeon satisfaction

Timepoint

Immediately after the block

Method of measurement

Questioning

4

Description

Patient satisfaction

Timepoint

Immediately after the block

Method of measurement

Questioning

5

Description

First analgesic dose

Timepoint

Every 30 minutes

Method of measurement

Clinical assessment

Intervention groups

1

Description

Control group (Group C): Includes 20 patients. Each will receive 9 ml of lidocaine 2% (containing 1 ml = 10 unit of hyaluronidase) + 1 ml of saline

Category

Other

2

Description

Intervention group 1 (Group N1): Includes 20 patients. Each will receive 9 ml of lidocaine 2% (containing 1 ml = 10 unit of hyaluronidase) + 0.5 mg of neostigmine

Category

Other

3

Description

Intervention group 2 (Group N2): Includes 20 patients. Each will receive 9 ml of lidocaine 2% (containing 1 ml = 10 unit of hyaluronidase) + 0.25 mg of neostigmine

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute of Ophthalmology

Full name of responsible person

Dr. Iman Sobhy

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Sponsors / Funding sources

1

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Full name of responsible person

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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

Contact
Name of organization / entity
Research Institute of Ophthalmology
Full name of responsible person
Dr. Iman Sobhy
Position
Consultant
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Medical doctor
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Anesthesiology
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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

Neostigmine in peribulbar block for cataract surgery IPD

set (all collected deidentified IPD).

When the data will become available and for how long

Beginning 6 months and ending 36 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 PI.

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

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

Comments