Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparative study between the analgesic effect of ketorolac when administrated intra-venous preoperatively versus when added to local anesthesia in squint surgery

Protocol summary

Study aim

To evaluate safety and efficacy of ketorolac regarding its analgesic effect as an adjuvant for peribulbar block in squint surgery, and whether it is better if administrated intravenously preoperatively or when combined with the local anesthetics.

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 squint 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. The control group will include 30 patients, each will receive lidocaine 2% (10 ml) + hyaluronidase (5 IU per ml). The intervention group 1 will include 30 patients, each will receive 30 mg of ketorolac half an hour before the surgery and the local anesthesia [lidocaine 2% (10 ml) with hyaluronidase (5 IU per ml)]. The intervention group 2 will include 30 patients, each will receive lidocaine 2% (10 ml) with hyaluronidase (5 IU per ml) plus ketorolac (4 mg per ml).

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210106049952N2**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**
Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Iman Sobhy

Name of organization / entity

Research Institute of Ophthalmology

Country

Egypt

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-15, 1400/08/24

Expected recruitment end date

2022-02-15, 1400/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative study between the analgesic effect of ketorolac when administrated intra-venous preoperatively versus when added to local anesthesia in squint surgery

Public title
Comparative study between the analgesic effect of ketorolac when administrated intra-venous preoperatively versus when added to local anesthesia in squint surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Squint surgery American Society of Anesthesiologists Physical Status I, II, or III 30 to 70 years-old

Exclusion criteria:
American Society of Anesthesiologists Physical Status IV Coagulopathy or use of anticoagulant therapy Infection at the site of the block Posterior staphyloma Allergy to the local anesthetic agent used Bronchial asthma or bradyarrhythmia Uncooperative patient or refusal to participate in the study

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

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 90 identical, opaque, letter-sized envelopes. We used rolls of household aluminum cooking foil that we cut into 90 sheets (of the same width as and twice the height of the envelope). We prepared 90 envelope-sized sheets of white paper and 90 envelope-sized sheets of single sided carbon paper. We wrote “Treatment A” on 30 paper sheets, “Treatment B” on another 30 sheets, and “Treatment C” on the last 30 sheet. To prepare 30 “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 30 “Treatment A” envelops the same way. We prepared 30 “Treatment B” envelops and 30 “Treatment C” envelops the same way as “Treatment A” envelops. The three sets of envelops 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 90. 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)
Double blinded

Blinding description
Participants and outcome assessors will be blinded to the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of the Research Institute of Ophthalmology

Street address
2 El Ahram Street

City
Giza

Postal code
12557

Approval date
2021-01-03, 1399/10/14

Ethics committee reference number
3-1-2021

Health conditions studied

1

Description of health condition studied
Peribulbar block in adult patients undergoing squint surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Onset of sensory block

Timepoint
Every 5 seconds after the block till complete loss of sensation

Method of measurement

Clinical assessment using gentle touching of the cornea with cotton swab

2

Description
Onset of motor block
Timepoint
Every 5 seconds after the block till complete loss of eye movement
Method of measurement
Clinical assessment using the 3-point score in four directions; where 0=no movement, 1=partial movement, and 2=complete movement (with total of 10)

3

Description
Duration of the block
Timepoint
Every 10 minutes following the block till full recovery of the movement
Method of measurement
Clinical assessment

4

Description
Postoperative pain
Timepoint
Immediately after the surgery, and 1 h, 2 h, 4 h, and 6 h later
Method of measurement
Visual analog scale (from 0 to 10; where 0=no pain and 10=severe pain)

5

Description
Time to the first analgesic dose
Timepoint
Immediately after the surgery and every 30 minutes
Method of measurement
Clinical assessment

Secondary outcomes

1

Description
Hemodynamics (heart rate, blood pressure, and oxygen saturation)
Timepoint
Baseline, immediately after the block, and every 10 min after the block
Method of measurement
Electronic vital signs monitor

2

Description
Patient satisfaction
Timepoint
At the end of the surgery
Method of measurement
Questioning and scoring (1=no pain felt, 2=no comment, 3=moderate discomfort, 4=severe pain)

3

Description
Surgeon satisfaction
Timepoint
At the end of the surgery
Method of measurement
Questioning and scoring (0=unsuccessful, 1=poor, 2=acceptable, 3=perfect)

4

Description
Adverse effects, such as pain on injection, allergy to the drugs used, or bronchospasm
Timepoint
Following the block
Method of measurement
Clinical assessment

Intervention groups

1

Description
Control group: Includes 30 patients. Each will receive lidocaine 2% (10 ml) with hyaluronidase (5 IU per ml).
Category
Other

2

Description
Intervention group 1: Includes 30 patients. Each will receive 30 mg of ketorolac half an hour before the surgery and the local anesthesia [lidocaine 2% (10 ml) with hyaluronidase (5 IU per ml)].
Category
Other

3

Description
Intervention group 2: Includes 30 patients. Each will receive lidocaine 2% (10 ml) with hyaluronidase (5 IU per ml) plus ketorolac (4 mg per ml).
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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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
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Dr. Iman Sobhy
Position
Consultant
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Person responsible for updating data

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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

Ketorolac in peribulbar block for squint 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 to be evaluated by an independent review committee identified for this purpose.

Comments