Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effectiveness of preoperative administration of intravenous Atropine and topical Tetracaine on the incidence and severity of Oculo Cardiac Reflex (OCR) in strabismus surgery

Protocol summary

Study aim

Comparison of the effect of intravenous Atropine and topical Tetracaine in the occurrence of Cardio-Ocular Reflex (COR) in Strabismus surgery.

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 120 patients. The lottery was used for randomization.

Settings and conduct

This is a three-blind randomized clinical trial that was conducted on 120 patients who were candidates for Strabismus surgery in Faiz Hospital, Isfahan. After the approval of the ethics committee of the university, if the entry criteria were met, the patients (or their guardians) were included in the study and if they were satisfied, they were randomly assigned to the groups. In each group, the desired intervention was applied and the patient's clinical symptoms were recorded. The clinical caregiver evaluating the symptoms was different from the person applying the intervention and did not know the type of intervention. Even though the patients were included in the study, they were not aware of the type of intervention applied, so they were all blind. The data analysts also did not know the type of intervention applied in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 10 to 70 years old, candidates for Strabismus surgery, ASA anesthesia class I and II
Non-entry criteria: medical sensitivity to Atropine, tetracaine, and artificial tears, history of cardiovascular diseases

Intervention groups

Intervention group A: Patients in this group received 0.5 mg of intravenous Atropine immediately after anesthesia. Intervention group B: Patients in this group received 3 to 5 drops of 0.5% Tetracaine in 4 directions on the eyeball immediately after anesthesia. Control group C: Patients in this group received 3 to 5 drops of artificial tears immediately after anesthesia.

Main outcome variables

Heart Rate; Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150106020588N8**
Registration date: **2022-08-13, 1401/05/22**
Registration timing: **retrospective**

Last update: **2022-08-13, 1401/05/22**
Update count: **0**

Registration date

2022-08-13, 1401/05/22

Registrant information

Name

Darioush Moradi Farsani

Name of organization / entity

Isfahan Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date
2020-06-20, 1399/03/31
Actual recruitment end date
2021-05-21, 1400/02/31
Trial completion date
2021-05-23, 1400/03/02

Scientific title
Comparison of the effectiveness of preoperative administration of intravenous Atropine and topical Tetracaine on the incidence and severity of Oculo Cardiac Reflex (OCR) in strabismus surgery

Public title
Comparison of the effects of Atropine and Tetracaine on Oculo Cardiac Reflex (OCR) in strabismus surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for Strabismus surgery Age 10 to 70 years ASA class I and II informed consent to enter the study
Exclusion criteria:
Allergic to Atropine, Tetracaine and artificial tears Cardiovascular diseases history
Age
From **10 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a simple randomized clinical trial in which patients entered the study groups by lottery; The medicines and placebo were placed in sealed, opaque, and similar form packets which were coded. Each code was also written on a piece of paper, folded, and placed inside a box. After entering the operating room, each patient took one of the papers out of the box; The pocket with the same number was the intervention that was applied to him. This process continued till the number of patients reached the desired one.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a triple-blind clinical trial; In this way, before obtaining consent, patients were informed about the study but didn't know which group they would be in and therefore were blind. Also, the researcher who recorded the patient's symptoms was different from the nurse who injected the drug and didn't know the type of drug and was blind. Analysts who analyzed the data collected during the study also didn't know the type of intervention applied in each group and were blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-06-11, 1399/03/22
Ethics committee reference number
IR.MUI.MED.REC.1399.332

Health conditions studied

1

Description of health condition studied
Strabismus
ICD-10 code
H50
ICD-10 code description
Other strabismus

Primary outcomes

1

Description
Heart Rate
Timepoint
Before induction, immediately after the induction of anesthesia and then every 5 minutes to 30 minutes, and then every 10 minutes until the end of the surgery
Method of measurement
ECG monitoring

2

Description
Blood Pressure
Timepoint

Before induction, immediately after the induction of anesthesia and then every 5 minutes to 30 minutes, and then every 10 minutes until the end of the surgery

Method of measurement

Sphygmomanometer

Secondary outcomes

1

Description

Surgery Duration

Timepoint

From the moment of surgical intervention to the end of eye dressing

Method of measurement

Timer

Intervention groups

1

Description

Intervention group 1: Patients in this group after inducting of anesthesia using 5 mg/kg of Thiopental sodium manufactured by Elixir Company, an amount of 0.5 mg/kg of Atracurium manufactured by Caspian Pharmaceutical Company, and the amount of 2 M/kg of Fentanyl manufactured by Aburihan Company, after preparing the eyes and allowing access to the operation site by the surgeon, they received 0.5 mg of Atropine manufactured by Caspian Pharmaceutical Company intravenously, as well as maintenance of anesthesia using Propofol 100 mg/kg/min was administered. the patient's symptoms were measured and recorded until the end of the operation and then during recovery.

Category

Prevention

2

Description

Intervention group 2: Patients in this group after inducting of anesthesia using 5 mg/kg of Thiopental sodium manufactured by Elixir Company, an amount of 0.5 mg/kg of Atracurium manufactured by Caspian Pharmaceutical Company, and the amount of 2 M/kg of Fentanyl manufactured by Aburihan Company, after preparing the eyes and allowing access to the operation site by the surgeon, They received 3 to 5 drops of 0.5% topical Tetracaine made by Sinadaro in 4 directions on the eyeball. as well as maintenance of anesthesia using Propofol 100 mg/kg/min was administered. the patient's symptoms were measured and recorded until the end of the operation and then during recovery.

Category

Prevention

3

Description

Control group : Patients in this group after inducting of anesthesia using 5 mg/kg of Thiopental sodium manufactured by Elixir Company, an amount of 0.5 mg/kg of Atracurium manufactured by Caspian Pharmaceutical Company, and the amount of 2 M/kg of Fentanyl manufactured by Aburihan Company, after preparing the eyes and allowing access to the operation site by the surgeon, They received 3 to 5 drops of Artificial tears made by Sinadaro in 4 directions on the eyeball. as well as maintenance of anesthesia using Propofol 100 mg/kg/min was administered. the patient's symptoms were measured and recorded until the end of the operation and then during recovery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Dariush Moradi Farsani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dariush Moradi Farsani

Position
Anesthesiologist /Faculty

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available