

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effectiveness of lidocaine and bupivacaine Sub-tenon injection in preventing oculocardiac reflex in strabismus surgery

Protocol summary

Study aim

Comparison of the effectiveness of lidocaine and bupivacaine Sub-tenon injection in preventing oculocardiac reflex in strabismus surgery

Design

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 120 patients who will be undergoing strabismus surgery will be enrolled. Eligible patients will be randomly allocated into two equal A and B groups by block randomization.

Settings and conduct

This study will be done in the Operating room and recovery. All of the drugs solution of this study will be prepared by only one person who is aware of the study's grouping, in 4 ml syringes in the same shape. Anesthesiologist, patients, and all medical staff that will collaborate in the study will not aware of the drug allocated to each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult Patients with ASA class I or II, age between the 18 and 60, who are Candidate for sub-tenon's block. Exclusion criteria: ASA class of III or IV, Positive history of heart disease, hyperthyroidism and coagulation disorders, Pregnant women and Patient refusal.

Intervention groups

Intervention group A: After induction of anesthesia, 4cc of bupivacaine (brand name Marcaine) will be injected into the sub-tenon space of the operated eye.

Intervention group B: After induction of anesthesia, 4 cc of lidocaine will be injected into the sub-tenon space of the operated eye.

Main outcome variables

Heart rate and Mean arterial pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230122057174N1**

Registration date: **2023-02-01, 1401/11/12**

Registration timing: **prospective**

Last update: **2023-02-01, 1401/11/12**

Update count: **0**

Registration date

2023-02-01, 1401/11/12

Registrant information

Name

Mehrdad Salari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

msalari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-01, 1401/12/10

Expected recruitment end date

2023-09-01, 1402/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of lidocaine and bupivacaine Sub-tenon injection in preventing oculocardiac reflex in strabismus surgery

Public title

Comparison of the effects of lidocaine and bupivacaine in preventing oculocardiac reflex in strabismus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA grade I or II (American Society of Anesthesiology classification) Patients between 18 and 35 years old
Candidate patients for Sub-Tenon's block

Exclusion criteria:

Patients with ASA grade III or IV (American Society of Anesthesiology classification) Positive history of heart disease Positive history of hyperthyroidism Positive history of coagulation disorders Pregnant women Patient refusal

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into two groups by block randomization. In this technique, a permutation block of size 6 will be made for patients of two groups A & B. In each block, equal numbers for two groups will be considered in alternative positions. Then 20 blocks of size 6 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block. block sequence will be prepare by www.Randomization.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

Identical syringes containing 4 ml of bupivacaine 0.5% or 4 ml of lidocaine 0.5% are provided by the first person, these drugs, which have the same color and size and in similar colors, are injected by the second person who is completely unaware of the contents of the syringes. The anesthesiologist, patients, and other personnel involved in the work are blinded to the drugs injected in this study. This study is double-blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz Medical School

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

713451978

Approval date

2022-12-18, 1401/09/27

Ethics committee reference number

IR.SUMS.MED.REC.1401.469

Health conditions studied

1

Description of health condition studied

Strabismus

ICD-10 code

H50.9

ICD-10 code description

Unspecified strabismus

Primary outcomes

1

Description

Heart rate

Timepoint

Every 5 minutes during the operation

Method of measurement

Monitoring

2

Description

Mean arterial pressure

Timepoint

Every 5 minutes during the operation

Method of measurement

Monitoring

3

Description

Pain

Timepoint

One hour after the operation

Method of measurement

Questionnaire and Numerical Pain Rating Scale (NRS)

4

Description

Nausea

Timepoint

One hour after the operation

Method of measurement

History taking

5

Description

Vomiting

Timepoint

One hour after the operation

Method of measurement

History taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: After induction of anesthesia, 4cc of bupivacaine (brand name Marcaine) will be injected into the subtenon space of the operated eye.

Category

Treatment - Drugs

2

Description

Intervention group B: After induction of anesthesia, 4 cc of lidocaine will be injected into the subtenon space of the operated eye.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Mohsen Dehghanpoor farashah

Street address

Khalili Street, Shiraz.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

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7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Dehghanpoor farashah

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Assistant Professor of Pediatric Anesthesiology
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policy

Study Protocol

No - There is not 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