

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sub-tenons bupivacaine on oculocardiac reflex during strabismus surgery and post-operative pain

Protocol summary

Summary

Oculo-cardiac reflex (OCR) defined as bradycardia induced by manipulation of extra-ocular muscles, is a serious complication during strabismus surgery which requires prevention and attention in management. purpose: In the present study we investigated efficacy of sub-tenon injection of bupivacaine in prevention of OCR and management of post-operative pain. method: 50 patients who are candidate for strabismus surgery will randomize in case (bupivacaine injection) and control (sterile saline injection) groups and standard strabismus surgery will perform for all cases. inclusion criteria included all 8-17 years old patients admitted in Khalili Hospital for strabismus surgery on orbital rectus muscles and Exclusion criteria included addiction, previous operation on same muscle, diabetic patients and mental retard patients. Occurrence and severity of OCR and post-operative pain were compared between two groups. Patients randomly receive sub-Tenon's injection of 0.1 ml of 0.5% bupivacaine solution or sterile saline which previously prepare in similar vials specify with codes unknown to the surgeon and the study executor who evaluate pain and monitored the patient during the operation for measurement of oculocardiac reflex. Injection of bupivacaine or placebo solution will perform using a curved blunt 19 gauge cannula. Surgical resection or recession of the medial or lateral rectus muscles start 5 minutes after sub-tenon injection through the same conjunctival aperture use for injection. Surgical technique will be similar for all patients (recess, resect or both) and the same surgeon perform the operations. During the operation, patients continuously monitor by electrocardiography, pulse oximetry, capnography and blood pressure. Pulse rate will be monitored during manipulation of the rectus muscles and the minimal recorded pulse rate will be used for measurement and comparison of oculocardiac reflex. Executor will scale patient's pain in recovery room as patients score it between 0-10. 10 is indicative of the

most severe pain imaginable and zero represents no feeling of pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091714694N1**

Registration date: **2015-05-24, 1394/03/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-24, 1394/03/03

Registrant information

Name

mohammad reza taleb nezhad

Name of organization / entity

Shiraz medical school

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

ghanim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-20, 1393/06/29

Expected recruitment end date

2015-09-20, 1394/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sub-tenons bupivacaine on oculocardiac reflex during strabismus surgery and post-operative pain

Public title

The effect of sub-tenons bupivacaine on oculocardiac reflex during strabismus surgery and post-operative pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all 8-17 years old patients admitted in Khalili Hospital for strabismus surgery on orbital rectus muscles Exclusion criteria: Addiction ; Previous operation on same muscle ; Diabetic patients ; Mental retard patients

Age

From **8 years** old to **17 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences central building,
Zand BLVD, Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2014-08-20, 1393/05/29

Ethics committee reference number

92-01-01-5808

Health conditions studied**1****Description of health condition studied**

Oculocardiac reflex during strabismus surgery and Post operation pain

ICD-10 code

H50.3

ICD-10 code description

Intermittent strabismus

Primary outcomes**1****Description**

Pain

Timepoint

30 minutes after operation an 10ur after

Method of measurement

By patients scoring between 1 to 10

2**Description**

Heart rate

Timepoint

Before stretching of rectus muscle and during stretching

Method of measurement

Monitoring

Secondary outcomes**1****Description**

Nausea, Vomiting

Timepoint

Immediately after surgery and 2days after surgery

Method of measurement

History taking

Intervention groups**1****Description**

1 time sub tenon injection of 0.1ml bupivacaine 5%(5mg in 100ml) in case group 5 minutes before starting surgery

Category

Treatment - Drugs

2**Description**

sub tenon injection of 0.1ml normal saline in control group

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Doctor Mohamad Reza Talebnejad

Street address

Khalili Hospital, Khalili Street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Doctor Sayed Basir Hashemi

Street address

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

City

Shiraz

Grant name

پایان نامه دانشجویی

Grant code / Reference number

010010

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Mohamad Reza Talebnejad

Position

Pediatric Ophthalmology and Strabismus / Head of

Research Center of Ophthalmology Poostchi

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

City

Shiraz

Postal code

7134814336

Phone

+98 71 3230 5410

Fax

+98 71 3233 7598

Email

talebmor@sums.ac.irtalebnejadmr@yahoo.com

Web page address

Psorc.sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Mohammad Reza Talebnejad

Position

Pediatric Ophthalmology and Strabismus

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

City

Shiraz

Postal code

7134997446

Phone

+98 71 3230 5410

Fax

+98 71 3233 7598

Email

Talebmor@sums.ac.irTalebnejadmr@yahoo.com

Web page address

Psorc.sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Mohamad Reza Talebnejad

Position

Pediatric Ophthalmology and Strabismus / Head of Research Center of Ophthalmology Poostchi

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Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

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Postal code

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Phone

+98 71 3230 5410

Fax

+98 71 3233 7598

Email

talebmor@sums.ac.irtalebnejadmr@yahoo.com

Web page address

Psorc.sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty