Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Review and Comparison of Long-term Outcome of Intermittent Exotropia Surgery in Adults in Two Different Group with General Anesthesia and sedation with Local Anesthesia with Adjustment during surgery

Protocol summary

Study aim

1- Comparison of the mean of deviation before and week 1 and month 6 after X(T) surgery in the group with general anesthesia 2- Comparing the mean of deviation before and week 1 and month 6 after X(T) surgery in the group with local anesthesia 3- Comparison of the frequency of surgery result (Orthotropia/overcorrection/undercorrection) in two studied groups

Design

single-masked randomized controlled trial with Two arm parallel group. A total number of 50 patients divided into two equal groups using computerized randomization

Settings and conduct

Feiz Teaching Hospital, Isfahan, Iran؛Subjects were randomly assigned to one of the following groups: first group underwent muscle surgeries under General Anestesia(GA); second group underwent the same muscle surgeries plus adjustable sutures under local anesthesia and IV sedation

Participants/Inclusion and exclusion criteria

Inclusion criteria Age over 18 years؛ Basic intermittent exotropia؛ below 60 prism diopters Exclusion criteria Neurological dificit؛ vertical muscle dysfunction؛ Patients with amblyopia؛ decreased visual acuity of any cause؛ history of strabismus or any other ocular surgery Abnormal ophthalmologic exam

Intervention groups

first group underwent definite muscle surgery including either bilateral lateral rectus recession (BLRc) or single lateral rectus recession (LRc) under GA; second group underwent the same muscle surgeries plus adjustable sutures under local anesthesia and IV sedation.

Main outcome variables

_ Pre- Angle of Deviation _ Post-Angle of Deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047271N1**
Registration date: **2022-09-20, 1401/06/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-20, 1401/06/29**
Update count: **0**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

Abolfazl Karimi Harandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4650 7283

Email address

akarimiharandi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Review and Comparison of Long-term Outcome of Intermittent Exotropia Surgery in Adults in Two Different Group with General Anesthesia and sedation with Local Anesthesia with Adjustment during surgery

Public title
" Review of Long term Outcome of Intermittent Exotropia Surgery with General Anesthesia in Adults":"Review of Long term Outcome of Intermittent Exotropia Surgery with sedation and Local Anesthesia with Adjustment during surgery in Adults "

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Basic intermittent exotropia below 60 prism diopters
Exclusion criteria:
Neurological dificit vertical muscle dysfunction Patients with amblyopia decreased visual acuity of any cause history of strabismus or any other ocular surgery Abnormal ophthalmologic exam

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization: A table with four columns and rows is prepared according to the number of patients, then people are placed in the houses of the table based on the toss of a coin, for this purpose, the Heads is assigned to the case group and the Tails is assigned to the control group. For example, if the coin toss is Heads-Tails, Heads-Tails, the four columns of the table are placed as case- control, case- control, and if the coin toss is Heads-Heads for the two patients, then for the next two patients There is no coin toss and they are placed in the control group and thus the number of samples is divided equally between the two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are not aware of their allocation to the study groups, but were randomly assigned to one of the two study groups by the researcher. The operation of all patients is known to the surgeon and only the type of anesthesia differs based on randomization.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Alley 40, 3rd dead end, Modarres St, Ghods Sq
City
Esfahan
Province
Isfehan
Postal code
8134167594

Approval date
2020-05-11, 1399/02/22

Ethics committee reference number
IR.MUI.MED.REC.1399.136

Health conditions studied

1

Description of health condition studied
Intermittent exotropia

ICD-10 code
H50.34

ICD-10 code description
Intermittent alternating exotropia

Primary outcomes

1

Description
Angle of Deviation : Quantitative amount of exotropia based on prism measurement with prism diopter (PD)

Timepoint
Before surgery and one week and six months after surgery

Method of measurement
prism cover test

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: underwent definite muscle surgery including bilateral lateral rectus recession (BLRc) under GA.GA was induced by administering a combination of propofol, succinylcholine,and

sevoflurane.BLRc , a limbal approach was taken to create a triangular conjunctival flap that extended toward the lateral rectus (LR) muscle. The LR was delineated and caught by a muscle hook and secured by two 6-0 Vicryl sutures on the upper and lower borders of muscle tendon. A caliper was further used to mark the new insertion site, which was established on to the sclera.

Category

Treatment - Surgery

2

Description

Second Intervention group: underwent the same muscle surgeries under local anesthesia and IV sedation.Tetracaine 1% was used for topical anesthesia . On the other hand, IV sedation was induced by administering acombination of IV benzodiazepines, propofol, and ketamine, where necessary

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz Teaching Hospital

Full name of responsible person

Abolfazl Karimi harandi

Street address

Quods Square, Modarres Street, Isfahan, Iran;

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansor siavash

Street address

Quods Square, Modarres Street, Isfahan, Iran

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Email

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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

Abolfazl Karimi harandi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

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Position
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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