

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing Medial rectus Advancement Using Non absorbable versus Absorbable Suture in patients with Consecutive Exotropia

Protocol summary

Study aim

To compare non absorbable and absorbable suture in patients with consecutive exotropia that undergo medial rectus muscle advancement.

Design

Two arm parallel group randomised and single blinded trial with blind postoperative care and outcome assessment

Settings and conduct

This study is conducted at Farabi Eye Hospital- Tehran University of Medical Sciences. The person, who will measure preoperative and postoperative angle of deviation will be kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Angle of consecutive exotropia more than 15 prism diopter; Consecutive exotropia cases that need single medial rectus advancement. Exclusion criteria: History of neurologic problems; Significant vertical deviation; Less than 4 months passed from previous surgery.

Intervention groups

In group 1 (case) medial rectus muscle advancement using non absorbable suture is applied. In group 2 (control) medial rectus muscle advancement using absorbable suture is considered.

Main outcome variables

Deviation, XT or ET

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190502043449N1**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **prospective**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

Amirreza Veisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 6283

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amirveisi3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Medial rectus Advancement Using Non absorbable versus Absorbable Suture in patients with Consecutive Exotropia

Public title

Consecutive exotropia treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consecutive exotropia following medial rectus recession

consecutive exotropia > 15 PD consecutive exotropia cases that need single medial rectus advancement

Exclusion criteria:

History of neurologic problems
Significant vertical deviation
Less than 4 M passed from previous surgery
Positive forced duction test

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization is permuted block randomization. The blocks of size 2, 4 and 6 will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single blinded. The person who assesses outcomes will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Farabi Eye Hospital, Tehran
University of Medical Sciences

Street address

Ghazvin square, South Kargar street

City

Tehran

Province

Tehran

Postal code

1336516351

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.TUMS.FARABIH.REC.1398.004

Health conditions studied

1

Description of health condition studied

Consecutive exotropia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

postoperative angle of deviation

Timepoint

3 months and 6 months

Method of measurement

Prism

Secondary outcomes

1

Description

recurrence of angle of deviation

Timepoint

Before surgery, 1 week, 3 months and 6 months after surgery

Method of measurement

Prism

Intervention groups

1

Description

Intervention group: medial rectus muscle advancement using nonabsorbable suture (Mersiline 6-0)

Category

Treatment - Surgery

2

Description

Control group: medial rectus muscle advancement using absorbable suture (vicryl 6-0)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi eye hospital

Full name of responsible person

Mohammadreza Akbari

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Ghazvin square, South Kargar street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Amirreza Veisi
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strabismus fellowship assistant
Latest degree
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Person responsible for updating data

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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

there is no further information

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

Yes - There is 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

study protocol will be shared when data are published

When the data will become available and for how long

at the sametime of data publication

To whom data/document is available

editor of journal

Under which criteria data/document could be used

no

From where data/document is obtainable

amirreza veisi Farabi eye hospital

What processes are involved for a request to access data/document

4 months may be needed

Comments