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
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

**Health conditions studied**

1. **Description of health condition studied**
   - Consecutive exotropia

2. **ICD-10 code**
   - ICD-10 code description

**Primary outcomes**

1. **Description**
   - postoperative angle of deviation

2. **Timepoint**
   - 3 months and 6 months

3. **Method of measurement**
   - Prism

**Secondary outcomes**

1. **Description**
   - recurrence of angle of deviation

2. **Timepoint**
   - Before surgery, 1 week, 3 months and 6 months after surgery

3. **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**
   - Farabi eye hospital

   **Full name of responsible person**
   - Mohammadreza Akbari

   **Street address**
   - Ghazvin square, South Kargar street
Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Akbari
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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
Position
strabismus fellowship assistant
Latest degree
Specialist

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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 same time 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