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

**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

Street address
Ghazvin square, South Kargar street
City
Tehran
Province
Tehran
Postal code
1336616351
Phone
+98 21 5540 0003
Email
amirveis3@gmail.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Akbari
Street address
Ghazvin square, South Kargar street
City
Tehran
Province
Tehran
Postal code
1336616351
Phone
+98 21 5540 0003
Email
amirveis3@gmail.com
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
Other areas of specialty/work
Ophthalmology
Street address
Ghazvin square, South Kargar street
City
Tehran
Province
Tehran
Postal code
1336616351
Phone
+98 21 5540 0003
Email
amirveis3@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amirreza Veisi
Position
Fellowship assistant
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
Ghazvin square, South Kargar street
City
Tehran
Province
Tehran
Postal code
1336616351
Phone
+98 21 5540 0003
Email
amirveis3@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amirreza Veisi
Position
strabismus fellowship assistant
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
Ghazvin square, South Kargar street
City
Tehran
Province
Tehran
Postal code
<table>
<thead>
<tr>
<th>Sharing plan</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Deidentified Individual Participant Data Set (IPD)</td>
<td>No - There is not a plan to make this available</td>
</tr>
<tr>
<td>Justification/reason for indecision/not sharing IPD</td>
<td>there is no further information</td>
</tr>
<tr>
<td>Study Protocol</td>
<td>Yes - There is a plan to make this available</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>No - There is not a plan to make this available</td>
</tr>
<tr>
<td>Informed Consent Form</td>
<td>No - There is not a plan to make this available</td>
</tr>
<tr>
<td>Clinical Study Report</td>
<td></td>
</tr>
</tbody>
</table>

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**