Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Extra ocular muscle fenestration as a weakening maneuver for surgical management of strabismus : A randomized pilot clinical trial

Protocol summary

Study aim
To evaluate the efficacy and safety of fenestration as a weakening maneuver to horizontal and vertical extra ocular muscles in the surgical management of strabismus

Design
Parallel group, controlled, randomized trial with 1:1 allocation ratio

Settings and conduct
Pediatric Ophthalmology and Strabismus Department at the Research Institute of Ophthalmology

Participants/Inclusion and exclusion criteria
We will include patients (male or female, from 1 to 60 years-old) with strabismus that requires surgical intervention with diagnosis after: 1. Complete routine ophthalmological evaluation. 2. Evaluation of the angle of strabismus to and deciding the amount of needed weakening. We will exclude patients with 1. with previous strabismus surgery upon the target muscle to be weakened. 2. with previous orbital surgery, orbital masses, or orbital inflammatory diseases.

Intervention groups
The rectus muscle will be exposed through a fornical conjunctival incision then the muscle will be stretched between 2 muscle hooks, and 2 peripheral muscle strips each 1 mm in width will be created using a fine muscle hook or by stripping the muscle fibers with a silk suture starting proximal at the desired site till the muscle insertion. The 2 muscle strips will then be separated on each side and the muscle belly in between will be excised leaving a bare sclera (a fenestration or a window defect). The conjunctiva will be re positioned.

Main outcome variables
1. Ocular alignment. 2. Ocular motility. 3. Conjunctival wounds.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200503047293N1**
Registration date: **2020-05-20, 1399/02/31**
Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**
Update count: **0**

Registration date
2020-05-20, 1399/02/31

Registrant information

Name
Sameh Galal
Name of organization / entity
Research Institute of Ophthalmology
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Egypt
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+20 2 35718304
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-01, 1399/03/12

Expected recruitment end date
2020-07-31, 1399/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Extra ocular muscle fenestration as a weakening maneuver for surgical management of strabismus : A

randomized pilot clinical trial

Public title
Extra ocular muscle fenestration for surgical management of strabismus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with strabismus that requires surgical intervention after complete routine ophthalmological evaluation and evaluation of the angle of strabismus
Exclusion criteria:
Previous strabismus surgery upon the target muscle
Previous orbital surgery, orbital masses, or orbital inflammatory diseases
Age
From **1 year** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use the sequentially numbered, opaque sealed envelopes method. We will use envelopes that are impermeable to intense light, and the allocation sequence will be concealed from the physicians enrolling and assessing participants. To prevent subversion of the allocation sequence, the name and hospital admission number of the participant will be written on the envelope. Carbon paper will transfer the information onto the allocation card inside the envelope. Corresponding envelopes will be opened only after the enrolled participants completes all baseline assessments and it is time to allocate the intervention.
Blinding (investigator's opinion)
Single blinded
Blinding description
Since it is an operative procedure, only participants will be blinded to the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethical Committee of the Research Institute of Ophthalmology
Street address
2 El Ahram Street
City
Giza
Postal code
12557
Approval date
2020-02-23, 1398/12/04
Ethics committee reference number
571/23-02-2020

Health conditions studied

1

Description of health condition studied
Strabismus
ICD-10 code
H50.9
ICD-10 code description
Unspecified strabismus

Primary outcomes

1

Description
Ocular balance (post operative ocular alignment)
Timepoint
Second day, one week, and one month post-operative
Method of measurement
By corneal light reflex, Krimisky test, and prism cover test

Secondary outcomes

1

Description
Ocular motility (freedom vs limitations)
Timepoint
Second day, one week, and one month post-operative
Method of measurement
Assessment of versions and ductions

2

Description
Post-operative pain
Timepoint
Second day, one week, and one month post-operative
Method of measurement
Asking the patient about post operative pain and giving a pain score from 1 to 5

Intervention groups

1

Description

Intervention group 1 (muscle fenestration): The rectus muscle will be exposed through a fornical conjunctival incision then the muscle will be stretched between 2 muscle hooks, and 2 peripheral muscle strips each 1 mm in width will be created using a fine muscle hook or by stripping the muscle fibers with a silk suture starting proximal at the desired site till the muscle insertion. Then, the 2 muscle strips will be separated on each side and the muscle belly in between will be excised leaving a bare sclera (a fenestration or a window defect). The conjunctiva will be re-positioned, and the surgery will be concluded.

Category

Treatment - Surgery

2

Description

Intervention group 2 (classic muscle recession): The muscle will be exposed by fornical incision. Dissection of the conjunctiva and tenon capsule will be done. Hooking of the muscle by Jameson hook and dissection of the intermuscular septum will be done. A Chavasse muscle hook will be exchanged with Jameson muscle hook, and the muscle will be secured with a coated double-armed Vicryl 6-0 suture with an s-29 needle. The desired amount of recession will be measured from the original insertion by a caliper. Scleral sutures will be taken at the superior and inferior edges parallel to the original insertion. The muscle will be pulled up to the level of the desired new insertion, making sure the sutures are taut and the muscle belly spreads nicely against the sclera. A knot will be tied with a double forehand throw, a single backhand throw, and a final single forehand throw. The sutures will then be cut 2 mm from knot. The conjunctiva is then closed with 2 interrupted Vicryl 8-0 sutures.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute of Ophthalmology

Full name of responsible person

Dr. Sameh Galal

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute of Ophthalmology

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Self-funded

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Research Institute of Ophthalmology

Full name of responsible person

Dr. Omar Hashem

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
No - There is not 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
Extra ocular muscle fenestration IPD set (all collected deidentified IPD)

When the data will become available and for how long
beginning 6 months and ending 36 months following article publication

To whom data/document is available
Researchers from academic institutions whose proposal for the use of data has been approved by an independent review committee identified for this purpose

Under which criteria data/document could be used
for IPD meta-analysis

From where data/document is obtainable
from the PI

What processes are involved for a request to access data/document
A proposal for the use of data to be submitted to the PI, then evaluated by an independent review committee identified for this purpose

Comments