

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of surgical result of horizontal rectus muscle elongation on large-angle strabismus in patients older than 4 years

#### Protocol summary

##### Study aim

surgical result of horizontal rectus muscle elongation on large-angle strabismus

##### Design

The intervention is performed on patients older than four years and large-angle horizontal strabismus ( $ET \geq 50PD$ ,  $XT \geq 60PD$ ) who had no history of strabismus surgery and whose deviation was not paretic or restrictive. These patients undergo muscle elongation surgery instead of conventional recession if indicated. Depending on the degree of deviation, this procedure is performed bilaterally or with resection of the antagonist muscle on the same side.

##### Settings and conduct

Interventional case series study on patients with large-angle horizontal strabismus ( $ET \geq 50PD$ ,  $XT \geq 60PD$ ) who undergo surgery within the next year (at least 5 patients). These patients undergo rectus muscle elongation surgery instead of conventional recession if indicated. Depending on the degree of deviation, this procedure is performed bilaterally or with resection of the antagonist muscle on the same side.

##### Participants/Inclusion and exclusion criteria

Age  $\geq 4$  years large-angle strabismus ( $ET \geq 50PD$ ,  $XT \geq 60PD$ ) Concomitant strabismus

##### Intervention groups

Horizontal rectus muscle elongation surgery on large-angle Horizontal strabismus

##### Main outcome variables

Correction rate of ocular deviation 2 weeks, 2 months, 6 months after surgery Correction rate of deviation relative to elongation rate, two weeks, 2 months, 6 months postoperatively Degree of restricted eye movements after surgery

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20220220054077N1**

Registration date: **2022-05-28, 1401/03/07**

Registration timing: **prospective**

Last update: **2022-05-28, 1401/03/07**

Update count: **0**

##### Registration date

2022-05-28, 1401/03/07

#### Registrant information

##### Name

ali norouzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3728 1400

##### Email address

dr.alinoroozi@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2022-06-05, 1401/03/15

#### Expected recruitment end date

2022-09-06, 1401/06/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of surgical result of horizontal rectus muscle elongation on large-angle strabismus in patients older than 4 years

## Public title

Surgical result of horizontal rectus muscle elongation on large-angle strabismus

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with large-angle strabismus (ET  $\geq$ 50PD, XT $\geq$ 60PD) Concomitant strabismus Age  $\geq$  4 years

### Exclusion criteria:

Paretic or restrictive strabismus History of strabismus surgery

## Age

From **4 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **13**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Medicine, Mashhad University of Medical Sciences

##### Street address

East door of the university campus, Azadi Square, Mashhad, Khorasan Razavi

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2022-02-07, 1400/11/18

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.732

## Health conditions studied

### 1

#### Description of health condition studied

large-angle exotropia

#### ICD-10 code

H501

#### ICD-10 code description

Exotropia (from Greek exo meaning "outward" and trope meaning "a turning"), also referred to as divergent squint, is a form of strabismus where the eyes are deviated outward. It is the opposite of esotropia. People with exotropia often experience crossed

### 2

#### Description of health condition studied

large-angle esotropia

#### ICD-10 code

H500

#### ICD-10 code description

Esotropia (from Greek eso meaning "inward" and trope meaning "a turning"), is a form of strabismus, or "squint," in which one or both eyes turns inward. The condition can be constantly present, or occur intermittently, and can give the affected individual

## Primary outcomes

### 1

#### Description

Angle of deviation

#### Timepoint

2 weeks, 2 months, 6 months after surgery

#### Method of measurement

Krimsky, modified Krimsky, Hirschberg, Alternate cover test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The width of the muscle is divided into 3 equal parts, one upper and lower third after sewing with 6-0 vicryl thread is cut from the insertion site and the middle part is cut to the end, which determines the amount of engagement according to the preoperative prediction. It is desired to be sewn. This procedure is performed bilaterally or with antagonist muscle resection on the same side. The choice of one-sided or two-sided operation will be based on the usual criteria. Alternate deviations or cases where the exotropia in far or the esotropia in near are more, preferably with bilateral surgery, and in cases of constant unilateral deviation, surgery will be performed

on one eye.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Khatam Ol-Anbia Eye Hospital

**Full name of responsible person**

Ali Akbar Sabermoghadam

**Street address**

Shahid Gharani Boulevard

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Mashhad

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kh.pr@mums.ac.ir

**Web page address**

https://khatam.mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayour Mobarhan

**Street address**

Shahid Fakouri Blvd

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Info.en@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Aliakbar Saber Moghaddam Ranjbar

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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**Person responsible for scientific inquiries**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Aliakbar Saber Moghaddam Ranjbar

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Postal code**

9195965919

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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