

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of anterior transposition of the inferior oblique muscle in the treatment of severe superior oblique muscle palsy

Protocol summary

Study aim

The effect of anterior transposition of the inferior oblique muscle in the treatment of severe superior oblique muscle palsy in

Design

Our study will take place within 18 months from the first of September 2016 to by the end of the 20 March of 2018. All subjects who had entered the study within one year and a half were included in the study as a non-control group in a full-scale study, with about 25-30 eligible for inclusion in the study.

Settings and conduct

Before surgery, the patient's deviation will be accurately calculated and compared with the amount of deviation in the eye after surgery. In this study, the reduction of shedding of eyes equal to or less than 4PD will be considered as a success. Patients entering the study will undergo anterior transposition of inferior oblique surgery. In all patients, one surgeon will be. These patients will be followed up regularly for 3 months after surgery. The latest tracking of information will be collected and analyzed. Post-operative examinations will be performed by someone else.

Participants/Inclusion and exclusion criteria

All patients diagnosed with severe superior oblique muscle palsy (greater than or equal to 20PD), candidates for anterior transposition of the inferior oblique muscle. Exit criteria include: previous operation on the muscles of the mule or vertebrae and bilateral paralysis of the upper shoulder muscle.

Intervention groups

All patients diagnosed with severe superior oblique muscle palsy (greater than or equal to 20PD), candidates for anterior transposition of the inferior oblique muscle.

Main outcome variables

Determine the amount of deviation of the eye before the anterior movement of the lower muscle. Determine the amount of deviation after the anterior movement of the lower muscle. Comparing the amount of deviation before

and after the anterior movement of the lower muscle.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038625N1**

Registration date: **2018-05-31, 1397/03/10**

Registration timing: **retrospective**

Last update: **2018-08-20, 1397/05/29**

Update count: **1**

Registration date

2018-05-31, 1397/03/10

Registrant information

Name

Ahmad Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2018-02-04, 1396/11/15

Trial completion date

empty	
Scientific title The effect of anterior transposition of the inferior oblique muscle in the treatment of severe superior oblique muscle palsy	City tabriz
	Province East Azarbaijan
	Postal code 5155956853
Public title The effect of anterior transposition of the inferior oblique muscle in the treatment of severe superior oblique muscle palsy	Approval date 2017-12-04, 1396/09/13
Purpose Treatment	Ethics committee reference number IR.TBZMED.REC.1396.776
Inclusion/Exclusion criteria Inclusion criteria: All patients diagnosed with severe superior oblique muscle palsy (greater than or equal to 20 PD), candidates for anterior transposition of the inferior oblique muscle ,will be included in the study after obtaining informed consent. Exclusion criteria: Exit criteria include: previous operation on the muscles of the mule or vertebrae and bilateral paralysis of the superior oblique muscle	Health conditions studied 1 Description of health condition studied The effect of anterior transposition of the inferior oblique muscle in the treatment of severe superior oblique muscle palsy ICD-10 code ICD-10 code description
Age No age limit	Primary outcomes 1 Description All patients with severe paralysis of the superior oblique muscle. have a high deviation of 20 PD in patients with severe deviation.
Gender Both	Timepoint Before starting the study
Phase N/A	Method of measurement prism
Groups that have been masked <i>No information</i>	Secondary outcomes empty
Sample size Target sample size: 30 Actual sample size reached: 30	Intervention groups 1 Description Intervention group: All patients diagnosed with severe superior oblique muscle palsy (greater than or equal to 20 PD), candidates for anterior transposition of the inferior oblique muscle ,will be included in the study after obtaining informed consent.A trial study was conducted without control group.
Randomization (investigator's opinion) N/A	Category Treatment - Surgery
Randomization description	Recruitment centers 1 Recruitment center Name of recruitment center medical education Eye Center Tabriz Nikokary Full name of responsible person
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 Ethics Committee of Tabriz University of Medical Sciences Street address Tabriz / Azadi Avenue / Golghast Street / Central University of Medical Sciences	

Dr. Reza Nabie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban . Ph.D

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Reza nabie

Position

Associate Professor, Department of Ophthalmology, Tabriz University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing results.

To whom data/document is available

For scholars working in academia

Under which criteria data/document could be used

There are no specific conditions for using data or documentation.lj

From where data/document is obtainable

Tabriz University of Medical Sciences. Ophthalmology Group

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

Department of Ophthalmology of Nicokary Hospita

Comments