

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of horizontal rectus muscle weakening by lateral rectus muscle marginal myotomy with medial rectus muscle recession in palpebral fissure height in duane retraction syndrome type1

Protocol summary

Study aim

The effect of horizontal rectus muscle weakening by lateral rectus muscle marginal myotomy with medial rectus muscle recession in palpebral fissure height in duane retraction syndrome type1

Design

Clinical trials with control group, with parallel groups, randomized

Settings and conduct

Twenty-eight patients referred to the Fifth Grade Strabism Center with type 1 Duane syndrome who needed rectus weakening surgery were selected easily and in a convenient way and then completely randomly assigned to two groups of 14 subjects. Surgery, 2 weeks and 3 months after surgery, the degree of deflection of the eye in the face position, the vertical deflection of the affected eye in front of the eye, and the extent of the narrowing of the affected eye eyelid with a view to the opposite side of the measurement Became Also abnormal head rotation was recorded based on the opinion of the physician and the parents of the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Detection of Type 1 Disease Syndrome Based on Diagnostic Criteria Age of the patient is 5 years or more The amount of distortion in the eye is less than 20 prisma diopters. The need for horizontal rectus muscle weakening Patient Satisfaction to Participate in the Study. Exclusion criteria: History of strabismus surgery There is an abnormal edge of the eyelid The presence of simultaneous neurological and chromosomal problems Other synchronous eye pathologies

Intervention groups

In the intervention group, the surgical intervention was performed in the form of a medial rectus withdrawal with marginal myometrium and in the surgical control group as a medullar rectus resection alone.

Main outcome variables

Distraction of the affected eye in front of the eye; Vertigo of the affected eye in front of the eye; narrowing of the affected eye lid gap in front of the eye; Abnormal head swing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131229015975N3**

Registration date: **2019-03-27, 1398/01/07**

Registration timing: **retrospective**

Last update: **2019-03-27, 1398/01/07**

Update count: **0**

Registration date

2019-03-27, 1398/01/07

Registrant information

Name

Mohsen Pourazizi

Name of organization / entity

Semnan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 23 1445 1385

Email address

m.pourazizi@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2018-02-19, 1396/11/30

Trial completion date

2018-02-19, 1396/11/30

Scientific title

The effect of horizontal rectus muscle weakening by lateral rectus muscle marginal myotomy with medial rectus muscle recession in palpebral fissure height in duane retraction syndrome type1

Public title

The effect of horizontal rectus muscle weakening by lateral rectus muscle marginal myotomy with medial rectus muscle recession in palpebral fissure height in duane retraction syndrome type1

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 1 Doyen syndrome based on diagnostic criteria: Restrictions on the horizontal movements of the eye, especially in abduction, eye drooping and eyedropic narrowing during up / down shoot of the eye during adduction. Age of the patient is 5 years or more The patient's age is 5 years or more. The amount of distortion in the eye is less than 20 prisma diopters. Need to weaken horizontal rectus muscles based on the diagnosis of an ophthalmologist Patient Satisfaction to Participate in the Study

Exclusion criteria:

History of strabismus surgery There is an abnormal edge of the eyelid The presence of simultaneous neurological and chromosomal problems Other synchronous eye pathologies

Age

From **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Actual sample size reached: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of patients was easy and accessible among patients with type 1 duine syndrome referring to Feyz Hospital in Isfahan, which has acceptable criteria. The patients were randomly assigned to two groups based on chance chances. In the operating room, envelopes containing recession paper and myotomy were placed in front of the patient and the patient entered one of the intervention groups by selecting one of the envelopes....

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

396503

Health conditions studied**1****Description of health condition studied**

Duane syndrome type1

ICD-10 code

H01.9

ICD-10 code description

Inflammation of eyelid, unspecified

Primary outcomes**1****Description**

The degree of deviation of the affected eye is in the face

Timepoint

Before surgery, two weeks and three months after surgery.

Method of measurement

Clinical examination by the same surgeon.

2**Description**

Vertical deviation of the affected eye in front of the eye

Timepoint

Before surgery, two weeks and three months after surgery.

Method of measurement

Clinical examination by the same surgeon.

3

Description

The amount of narrowing of the affected eye lid in front of the eye

Timepoint

Before surgery, two weeks and three months after surgery.

Method of measurement

Clinical examination by the same surgeon.

4

Description

Abnormal head rotation

Timepoint

Before surgery, two weeks and three months after surgery.

Method of measurement

Clinical examination by the same surgeon and patient report or his parents.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 14 patients diagnosed with ophthalmologist diagnosed with duine type 1 syndrome were selected to resolve the problem of eyelid narrowing, medial rectus medial intervention with marginal micectomy, and face-to-face factors (primary position), the vertical deviation of the affected eye in front of the eye, the degree of narrowing of the affected eyelid gap in front of the eye, and abnormal spinal rotation before, two weeks and three months after surgery, and it is registered.

Category

Treatment - Surgery

2

Description

Control group: 14 patients diagnosed with ophthalmologic diagnosis of type 1 duine syndrome were diagnosed and treated for rectus medication, and interventional rectus medication was used for solving the problem of eyelid narrowing. Primary position), the vertical deviation of the affected eye in front of the eye, the degree of narrowing of the affected eyelid gap in front of the eye and abnormal spinal rotation were measured and recorded before, two weeks and 3 months after surgery. .

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz Hospital in Isfahan

Full name of responsible person

Alireza Zandi

Street address

Quds Squ.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

dr_zandi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohsen Pourazizi

Position

M.D.

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

m.pourazizi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Zandi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

dr_zandi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Arman Amirkhani

Position

M.D.

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

dr_zandi@yahoo.com

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

Individual data of the participants can be made available to applicants after being unidentifiable and two years after the publication of the results.

When the data will become available and for how long

Two years after the publication of the results

To whom data/document is available

Specialists and assistants of the Eye Surgery Group.

Under which criteria data/document could be used

To compare the same method with the proposed method in this study

From where data/document is obtainable

Send a clear request to dr_zandi@yahoo.com and with the permission of the research and student deputy of the Isfahan University of Medical Sciences.

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

Send a clear request to dr_zandi@yahoo.com and with the permission of the research and student deputy of the Isfahan University of Medical Sciences.

Comments