

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

A clinical trial on the correction of ocular deviation in operation on new extra ocular muscles compare with re-operation on the same Extra ocular muscles used in previous surgery in treatment of Consecutive and Residual esotropia and exotropia

Protocol summary

Study aim

comparison between result of surgery on virgin muscles versus surgery on manipulated muscles in treatment of residual and consecutive esotropia and exotropia

Design

24 patients, one by one distributed in virgin muscles group or manipulated muscles group (in two groups of 12 patients), study was single blinded, enrollment time was between 2013 and 2017 and follow up for 3 months after surgery,

Settings and conduct

telephone call makes for all patient who had a BMR, BLR or R&R surgery more than six month ago, among those who had a surgery between April 2013 and April 2017 in Arvand or Imam Khomeini hospital in Ahvaz, more than six months ago, those had a consecutive XT, consecutive ET, residual XT or residual ET more than 15 prism diopter are included in the study. nystagmus, refraction, hypertropia, DVD, A or V pattern along with sex, amblyopia, number of previous surgeries, are documented for each patient. All patients are operated by same oculoplastic and strabismus surgeon by standard method and no further risk is carried on patients. Outcome are documented in 1 and 3 month after surgery. Blinding of study is done in analyzers (information survey committee).

Participants/Inclusion and exclusion criteria

patients with a history of BMR, BLR or R&R surgery, in Imam Khomeini or Arvand hospital, in Ahvaz, at least 6 month ago who have a residual or consecutive esotropia or exotropia are included. Patients with muscle fibrosis, Duan's syndrome, Brown's syndrome, traumatic deviation or those who can't come for 3 month follow up are excluded.

Intervention groups

in virgin extra ocular muscles group, based on standard

tables, disinsertion, replacement and reinsertion to new site on sclera is done in manipulated extra ocular muscles group, based on standard tables, disinsertion, replacement and reinsertion to new site on sclera is done

Main outcome variables

Post operative deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082135295N1**

Registration date: **2017-08-21, 1396/05/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-18, 1397/01/29**

Update count: **1**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name

mohammad saeed shakari

Name of organization / entity

ahvaz jondishapoor university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 8076

Email address

shakari.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

ahvaz jondi shaoor university of medical science

Expected recruitment start date

2013-08-16, 1392/05/25

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2013-08-16, 1392/05/25

Actual recruitment end date

2017-10-23, 1396/08/01

Trial completion date

empty

Scientific title

A clinical trial on the correction of ocular deviation in operation on new extra ocular muscles compare with re-operation on the same Extra ocular muscles used in previous surgery in treatment of Consecutive and Residual esotropia and exotropia

Public title

Study of surgical outcome on new extra ocular muscles and re-operation on the same Extra ocular muscle use in previous surgery in Residual and consecutive strabismus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Among those had a visit in Arvand or Imam khomeini hospital, patients with a history of six month or more of squint surgery including BMR(bimedial rectus muscle)surgery, or R&R(resection and recession) ,and had a consecutive exotropia, or residual esotropia more than 15 prism diopters Among those had a visit in Arvand or Imam khomeini hospital, patients with a history of six month or more of squint surgery including BLR(bilateral lateral rectus muscle)surgery, or R&R(resection and recession) ,and had a consecutive esotropia, or residual exotropia more than 15 prism diopters

Exclusion criteria:

patients with muscle fibrosis Duan syndrome Brown syndrome Traumatic deviation patients who can't come at least for 3 month of follow up

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **24**Actual sample size reached: **24****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

patients are distributed in groups one by one according

to time of first visit

Placebo

Not used

Assignment

Single

Other design features

sampling is census

Secondary Ids

empty

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

Ethics committee of deputy of research and technology development of Ahvaz jondoshapoor University o

Street address

ahvaz,city univercity.deputy of research and technology development,ahvaz jondishapoor university of medical science

City

ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2017-07-22, 1396/04/31

Ethics committee reference number

IR.AJUMS.REC.1396.374

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

esotropia,exotropia

ICD-10 code

H50.0,H50.

ICD-10 code description

Exotropia (alternating)(monocular), except intermittent,v

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

horizontal deviation after surgery

Timepoint

before, 1 month ,three month later

Method of measurement

deviation measured as prism diopter with krimski and hirschburg method

2**Description**

hypertropia

Timepoint

before, 1 month ,three month later

Method of measurement

deviation measured as prism diopter with krimski and hirschburg method

3

Description

Dissociated Vertical Deviation(DVD)

Timepoint

before, 1 month ,three month later

Method of measurement

deviation measured as prism diopter with krimski and hirschburg method

4

Description

nystagmus

Timepoint

before, 1 month ,three month later

Method of measurement

indirect ophthalmoscopy,or watch patient's eye without aid

5

Description

refraction

Timepoint

before, 1 month ,three month later

Method of measurement

diopter of refractive error measured by autorefractometer or retinoscopy

Secondary outcomes

1

Description

residual or consecutive deviation

Timepoint

1month,3month after surgery

Method of measurement

deviation measured as prism diopter by krimski and hirschburg method

2

Description

conjunctival cyst or granuloma

Timepoint

1month,3month after surgery

Method of measurement

slit lamp examination

Intervention groups

1

Description

in intervention group,surgery is performed on extra ocular muscles previously used in BMR,BLR or R&R surgery.standard fornix based conj peritomy is performed,then muscle sutured with vicryl6/0 then cut and based on a standard schedule sutured to sclere.then conjunctival suturing with vicryl6/0 performed.and eye ointment tetracyclin and eye patch is applied.all surgeries is performed by single strabismus and oculoplastic surgeon.

Category

Treatment - Surgery

2

Description

in control group,surgery is performed on new extra-ocular muscles (virgin muscles).standard fornix based conj peritomy is performed,then muscle sutured with vicryl6/0 then cut and based on a standard schedule sutured to sclere.then conjunctival suturing with vicryl6/0 performed.and eye ointment tetracyclin and eye patch is applied.all surgeries is performed by single strabismus and oculoplastic surgeon.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

professor gholamreza khtaminia

Street address

ahvaz,24 metri street,imam khomeini hospital,eye ward

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

dr behzad sharif makhmalzade,deputy of research and technology development

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ahvaz,city university,deputy of research and technology development

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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

Ahvaz 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 scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

dr gholamreza khataminia

Position

full professor oculoplastic and strabismus surgery

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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<http://fmedicine.ajums.ac.ir/HomePage.aspx?TabID=14720&Site=fmedicine.ajums.ac&Lang=fa-IR>

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

mohammad saeed shakari

Position

ophthalmology resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

mohammad saeed shakari

Position

ophthalmology resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no information

Study Protocol

No - There is not 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

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

results will be available in thesis

When the data will become available and for how long

since thesis was printed

To whom data/document is available

both scientific centers and faculty members

Under which criteria data/document could be used

as a reference for other studies

From where data/document is obtainable

email:shakari.m@ajums.ac.ir

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

monthly mail box will be checked

Comments