Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 april2013 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 patient 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 analizers(information survey commette).

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)

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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 hostpital, 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 hostpital, 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 size
Target 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
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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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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 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
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http://fmedicine.ajums.ac.ir/HomePage.aspx?TabID=14720&Site=fmedicine.ajums.ac&Lang=fa-IR

Person responsible for updating data

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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 refrence 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
monthy mail box will be checked
Comments