

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

**Investigating the effect of inferior oblique muscle myectomy along with superior rectus muscle reses with inferior oblique muscle myectomy combined with upper rectus z-tenotomy by microsurgery (MICS) method on the amount of vertical deviation in patients with inferior oblique muscle hypertrophy more than 8-10 prism diopters : clinical trial**

### Protocol summary

#### Study aim

Comparison of the effect of combined surgery of inferior oblique muscle myectomy and superior rectus muscle recession with combined surgery of inferior oblique muscle myectomy and z\_tenotomy using the upper right muscle MIS method in inferior oblique muscle hyperfunction more than 8-10 prism diopters

#### Design

Clinical trial with random permutation method, phase 3 on 60 patients, which was used for randomization using SPSS version 26 software.

#### Settings and conduct

After obtaining informed consent from the participants and after fully explaining the study to the patients at Imam Khomeini Hospital, it will be performed on patients with primary and secondary inferior oblique muscle hypertrophy whose primary position deviation is above 12 prism diopters. .

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with primary and secondary inferior oblique muscle hyperfunction whose primary position deviation is above 12 prism diopters. Exclusion criteria: People who had neurological and muscular diseases, patients who underwent eye surgery in the past, and also people who do not follow up regularly, will be excluded from the study.

#### Intervention groups

In the first group, lower oblique muscle myectomy and upper rectus muscle recession, and for the second group, a combined surgery of lower oblique muscle myectomy and z-tenotomy using the upper rectus muscle MIS method is performed in a minimally invasive way.

#### Main outcome variables

Degree of vertical deviation in patients

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20240121060751N1**

Registration date: **2024-02-02, 1402/11/13**

Registration timing: **prospective**

Last update: **2024-02-02, 1402/11/13**

Update count: **0**

#### Registration date

2024-02-02, 1402/11/13

#### Registrant information

##### Name

Seyede mina Mousavi nezhad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 748 4498

##### Email address

mousavinezhad.m@ajums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2024-02-07, 1402/11/18

#### Expected recruitment end date

2025-01-07, 1403/10/18

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty  
**Trial completion date**  
empty

### Scientific title

Investigating the effect of inferior oblique muscle mycotomy along with superior rectus muscle reses with inferior oblique muscle mycotomy combined with upper rectus z-tenotomy by microsurgery (MICS) method on the amount of vertical deviation in patients with inferior oblique muscle hypertrophy more than 8-10 prism diopters : clinical trial

### Public title

Comparison of the effect of combined surgery of inferior oblique muscle myectomy and superior rectus muscle recession with combined surgery of muscle myectomy and inferior oblique muscle myectomy combined with z-tenotomy of superior rectus muscle by microsurgery method (MICS)

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All patients with primary and secondary inferior oblique muscle hypertrophy whose primary position deviation is above 10 prism diopters.

#### Exclusion criteria:

People who had neurological and muscular diseases, patients who underwent eye surgery in the past, and also people who do not follow up regularly, will be excluded from the study.

### Age

No age limit

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, patients will be divided into two groups using the random permutation method. The method of assigning the intervention to patients is randomly and by the method of randomized permutation blocks with random block sizes of 4, 6 and 8 (using the table related to random permutations). The randomization list is prepared by a statistician. The intervention used in this research is allocated according to a randomized list.

### 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

Research Ethics Committee of Jundishapur University of Medical Sciences, Ahvaz

#### Street address

Jundishapur University of Medical Sciences, Koi Golestan, Ahvaz

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6193673166

### Approval date

2024-01-13, 1402/10/23

### Ethics committee reference number

IR.AJUMS.REC.1402.546

## Health conditions studied

1

### Description of health condition studied

Mycotomy surgery of the inferior oblique muscle

### ICD-10 code

H51.8

### ICD-10 code description

Other specified disorders of binocular movement

## Primary outcomes

1

### Description

Degree of vertical deviation in patients

### Timepoint

After the operation, it will be the first, third and seventh day and the third and sixth month. Orthopedic examinations applied before surgery will be repeated in the follow-ups and the results will be recorded. All patients will be operated by one surgeon.

### Method of measurement

If there is, the amount of deviation through the prism cover test

## Secondary outcomes

1

### Description

visual acuity

### Timepoint

After the operation, it will be the first, third and seventh day and the third and sixth month. Orthopedic

examinations applied before surgery will be repeated in the follow-ups and the results will be recorded. All patients will be operated by one surgeon.

#### **Method of measurement**

Using Snellen's chart and on pre-school age patients, cooperation level will be measured by finger counting method.

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The first group is lower oblique muscle myectomy and upper rectus muscle recession

#### **Category**

Treatment - Surgery

### **2**

#### **Description**

For the second group, the combined surgery of inferior oblique muscle myotomy with minimally invasive spinal surgery (MIS) of the superior rectus muscle is performed minimally.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital

##### **Full name of responsible person**

Gholamreza Khataminia

##### **Street address**

24 metery street, east sahely highway, ahvaz

##### **City**

Ahvaz

##### **Province**

Khouzestan

##### **Postal code**

6193673166

##### **Phone**

+98 916 111 0870

##### **Email**

khataminia@Hotmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Mehrnoosh Zakerkish

##### **Street address**

University of medical science, Golestan street, Golestan town, Ahvaz

##### **City**

Ahvaz

##### **Province**

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##### **Email**

khataminia@Hotmail.com

#### **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**

Gholamreza Khataminia

##### **Position**

Professor of Ophthalmology

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Ophthalmology

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## **Person responsible for scientific inquiries**

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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