

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the efficacy of extraocular myofascial technique on non-accommodative Eso deviations

Protocol summary

Study aim

evaluation of the effect size of extraocular myofascial release technique on the angle of deviation in non-accommodative Eso deviations

Design

A self-controlled clinical trial, single-arm, phase 2-3

Settings and conduct

Patients with non-accommodative Eso deviation due to convergence spasm remain without treatment intervention for a week after measuring the deviation near and far. At the end of the no-treatment week, the angle of deviation and the saccades' velocity will be measured. Then, the treatment intervention (extraocular myofascial release technique) is performed in two stages during one week for both eyes. At the end of this week, the angle of deviation and the saccades' velocity will be measured again, and their results will be compared.

Study location: Optometry Clinic, School of Rehabilitation, Iran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Participants: Young people with convergence spasm
Inclusion criteria: Age: 20 to 35 years Cyclofraction less than +1.00 D Visual acuity of 20/20 or better with correction Esophoria or Esotropia at near or far after complete refractive correction Normal AC/A ratio (2.86 ± 2.40) (Mean \pm SD) Comitancy of the deviation angle The occurrence of deviation or related symptoms in less than one year
Exclusion criteria: Use of any drug affecting the central nervous system Any underlying disease and drug usage History of the head or eye trauma History of strabismus surgery

Intervention groups

Patients with non-accommodative Eso deviation due to convergence spasm remain without therapeutic intervention for a week (control). Then the therapeutic intervention (releasing myofascial tissue for the medial rectus and related connective tissue for at least 300 seconds for each eye) is performed in two stages during the following week (intervention).

Main outcome variables

The magnitude of Eso deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050183N1**

Registration date: **2021-02-15, 1399/11/27**

Registration timing: **prospective**

Last update: **2021-02-15, 1399/11/27**

Update count: **0**

Registration date

2021-02-15, 1399/11/27

Registrant information

Name

Alireza Mohamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 8565

Email address

alremone@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of extraocular myofascial technique on non-accommodative Eso deviations

Public title

Effect of extraocular myofascial technique in treatment of strabismus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Less than +1.00 D cyclo-refraction Corrected visual acuity of 20/20 or better Esophoria or Esotropia at far or near after complete refractive correction Normal gradient AC/A ratio (2.86±2.40) (Mean ± SD) Comitancy in angle of deviation Recent onset of the deviation or its symptoms (less than one year ago)

Exclusion criteria:

Improper use of spectacle glasses (if the subject has a refractive error) Use of any drug affecting the central nervous system during study period Any underlying disease and drug usage History of the head or eye trauma History of strabismus surgery Suffering COVID-19 or any symptoms of the disease

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

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 Iran University of Medical Sciences

Street address

Fifth Floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway between Chamran and Sheikh Fazlollah

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.IUMS.REC.1399.1241

Health conditions studied

1

Description of health condition studied

Non-accommodative Esotropia due to spasm of convergence

ICD-10 code

H50.0

ICD-10 code description

Convergent concomitant strabismus

2

Description of health condition studied

Non-accommodative Esophoria due to spasm of convergence

ICD-10 code

H50.5

ICD-10 code description

Heterophoria

Primary outcomes

1

Description

Magnitude of the Eso deviation

Timepoint

At the initial visit - after one week without treatment - after one week of therapeutic intervention

Method of measurement

Cover-test and Prism bar

Secondary outcomes

1

Description

Saccadic Movement Velocity

Timepoint

After one week without treatment - after one week of therapeutic intervention

Method of measurement

Dynamic Electrooculography

Intervention groups

1

Description

Intervention group: In the first week, we will have no treatment; then, the therapeutic intervention will be done. It includes the myofascial release technique for the medial rectus muscle and its related connective tissue for at least 300 seconds per eye twice in a week for both eyes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor eye hospital

Full name of responsible person

Alireza Mohamadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Syed Abbas Motevallian

Street address

The fifth floor of the headquarters Iran University of Medical Sciences, Hemmat Highway next to Milad Tower

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Alireza Mohamadi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Optometry

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Person responsible for scientific inquiries

Contact

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Professor

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Other areas of specialty/work

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Position

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Latest degree

Master

Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

After de-identifying the IPD will be shared.

When the data will become available and for how long

Access starts two years after the results are published

To whom data/document is available

All

Under which criteria data/document could be used

0

From where data/document is obtainable

0

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

0

Comments