

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of orthoptics therapeutic effects using Major Amblyoscope (office-based therapy) as well as active vision therapy using Enhancement of binocular vision software and red-green glasses (home-based therapy) to improve controlling of intermittent exotropia

Protocol summary

Study aim

Evaluation of the effect of orthoptical treatment using major amblyoscope and also active vision therapy using binocular enhancement software and red-green glasses in improving intermittent exotropic control

Design

Clinical trial with intervention group using orthoptical exercises and binocular enhancement software and control group with conventional patch therapy treatment, simple randomized, phase 3 on 60 patients

Settings and conduct

Khatam Al-Anbia Ophthalmology Hospital, Mashhad The clinical trial is Superiority, Parallel and one-sided blind After eye examinations, we sit behind the major amblyoscope and use different slides such as simultaneous perception, flat fusion and fusion. At home, exercises such as removing suppression and pencil push up, Practice with 2 pencils, Marsden dot, thread and bead are done With good control after 1 month, follow-up for 6 months, and after there was no report of XT, the exercises are slowly reduced

Participants/Inclusion and exclusion criteria

- 5- 18 years Exotropia less than 40 prisms without vertical deviation or pattern no eye surgery, amblyopia & structural disorders and high refractive errors Gaining consent of the parents and child cooperation Grade 2, 3 & 4 on the Mohnsey and Holms IXT Control Scale - no cooperation of child

Intervention groups

In the intervention group, anti-suppression and fusion therapy exercises are performed by major amblyoscope and binocular enhancement software and red-green glasses 22 sessions and two 20-min sessions per week by an orthoptist. Playing computer games using filter glasses for 30 min twice a day for 5 days a week for 4 weeks and then 2 days a week for 8 weeks for 3 months

Main outcome variables

Intermittent and fusion state exotropic control based on the Mohnsey and Holmes Intermittent Exotropia Control Scale system evaluates this score before the intervention and then during subsequent follow-up times

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052668N1**

Registration date: **2021-11-08, 1400/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-08, 1400/08/17**

Update count: **0**

Registration date

2021-11-08, 1400/08/17

Registrant information

Name

Maryam Hedayati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-26, 1400/04/05

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of orthoptics therapeutic effects using Major Amblyoscope (office-based therapy) as well as active vision therapy using Enhancement of binocular vision software and red-green glasses (home-based therapy) to improve controlling of intermittent exotropia

Public title

Evaluation of the effect of eye exercises with the device in the clinic as well as active vision therapy at home using a computer game that enhances vision simultaneously with two eyes and special glasses at home in improving the intermittent deviation of the eye outwards

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age group 5-18 years Exotropia less than 40 prisms Intermittent exotropia without significant vertical deviation or pattern فقدان آمبلیوپی فقدان اختلالات ساختمانی + چشمها و عیوب انکساری بالا (میوپی بالای 6 - و هیپروپی بالای 5/4 Obtaining the informed consent of the parents and the existence of cooperation in the child Having grades 2, 3 and 4 on the Mohny and Holms IXT Control Scale

Exclusion criteria:

Lack of cooperation between parents and patients in the continuation of prescribed treatment

Age

From 5 years old to 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization will be done using a random number table and the website WWW.Randomization.com. Random concealment will be done using packets in the package in which the envelopes are prepared by a member of the research team and the random numbers extracted from WWW.Randomization.com are prepared and printed and They are placed inside the envelope and will be closed in the envelopes and its contents will not be visible from the outside; Then, first the purpose of the study will be explained to the person who has the inclusion criteria

and the person will sign the informed consent form and take an envelope and then open it and based on the contents of the envelope in the intervention or control group will enter.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor means that the person who visits the patient and evaluates and records the consequences is not aware of how the patients are grouped. In other words, the outcome assessor of the patient who visits and evaluates the outcome is not aware that the patient is Comments are in the control group or in the intervention group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Faculty of Medicine, Mashhad University of Medical Sciences

Street address

No.37, Kosar Blvd, south Kosar between 7 & 9

City

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Province

Razavi Khorasan

Postal code

9178156761

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.335

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

Intermittent exotropia

ICD-10 code

H50.34

ICD-10 code description

Intermittent alternating exotropia

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

Intermittent exotropia control score

Timepoint

Before the intervention, one and a half months, three months and six months after starting treatment

Method of measurement

Based on the Mohny and Holmes Intermittent Exotropia Control Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Anti suppression and fusion therapy exercises are performed by major amblyoscope (in the presence of the clinic) and software for enhancing binocular vision and red-green glasses (as a practice at home) at the same time. The treatment is performed using Hagg Streit 2003 model major amblyoscope with the following program. In this way, a total of 22 sessions per patient and two sessions per week for twenty minutes by an experienced orthoptist. Each session will take between 20-30 minutes, depending on the patient. In the next three months of follow-up, patients will not receive special treatment. (Except for the necessary corrective glasses) and child playing computer games using filter glasses to stimulate both eyes at the same time at home that Patients (with the help of their parents) are asked to take 30 minutes twice a day (one hour a day) for 5 days a week for 4 weeks and then two days a week for 8 weeks (36 hours in total). The child should use computer games for three months.

Category

Treatment - Devices

2**Description**

The control group is patients undergoing more common anti suppression therapy with patch therapy. The duration of patch therapy in these patients will be 1 to 2 hours per day, depending on the doctor's opinion (regarding the predominant eye and the division of closing hours between the two eyes alternately). This treatment is done for 5 months and no treatment is done in the sixth month. (Except for the necessary corrective glasses)

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khatam Al-Anbia Eye Hospital

Full name of responsible person

Mohammad Etezzad Razavi

Street address

Khatam Al-Anbia Eye Hospital, Aboutaleb Intersection

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Khalil Abnous

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Etezzad Razavi

Position

professor

Latest degree

Subspecialist
Other areas of specialty/work
Ophthalmology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

No - There is not 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

Individual Participant Data Set (IPD): all collected deidentified IPD could be shared.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

No further criteria.

From where data/document is obtainable

Mohammad Etezzad Razavi: Khatam al-Anbia Eye Hospital, Aboutaleb Intersection, Mashhad, Iran
etezadm@mums.ac.ir , 00989155199624

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

With a reasonable request, the data would be shared via email.

Comments