Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of orthoptics thraputic 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 orthopthic 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 orthopthic 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 aand pencil push up, Practice with 2pencils, Marsen dot, thread and bead are done With good control after 1month, 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 Mohney 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 orthopthist. 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 Mohney 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
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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 thraputic 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 بالای6 - 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 Mohney 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
Mashhad
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 Mohney and Holmes Intermittent Exotropia Control Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Anti suppresion 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 orthopthist. 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 suppresion 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 Etezad Razavi
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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
Street address
Ghoreyshi building, Daneshgah Ave.
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ramresearch@mums.ac.ir
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 Etezad Razavi
Position
professor
Latest degree

Subspecialist
Other areas of specialty/work
Ophthalmology
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Person responsible for updating data

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Mohammad Etezad Razavi
Position
Professor
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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 Etezad 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