Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation the Effect of Active Vision Therapy on visual skills using Vision Therapy System 4 (VTS4) in children with Bilateral Refractive Amblyopia ages 5-13

Protocol summary

Study aim
General objectives: Determining the effect of active vision therapy(AVT) using vision therapy system version 4 in children with bilateral refractive amblyopia(BRA)

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 40 patients. (Block randomization)

Settings and conduct
Selection of bilateral refractive amblyopia patient, aged 5-13 years, as available in Postachi clinic They will be referred to the Soroosh optometry center for full examination(VA, SA, CS, AI) Program for treatment group will be three 30-minute sessions AVT per week with patching. The control group will have patch and placebo vision therapy sessions. Difference consideration: at least one line improvement in VA. patients and optometrists who check before and after test will be blinded.

Participants/Inclusion and exclusion criteria
inclusion criteria: age between 5 - 13 years Astigmatism or hyperopia in each eye or a mix hyperopia-astigmatism Maximom VA 20/40 and Minimum VA 20/100 in each eye exclusion criteria: weak follow-up for treatment. The existence of pathological and structural problems of the eyes History of eye surgeries strabismus, microtropia or eccentric fixation

Intervention groups
AVT for the treatment group and patching for control group. for Treatment group active vision exercises and patching, for control group, patching and placebo training

Main outcome variables
Improvement of visual acuity, stereacuity, contrast sensitivity and facility of accommodation.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230823059229N1**
Registration date: **2024-02-28, 1402/12/09**
Registration timing: **prospective**

Last update: **2024-02-28, 1402/12/09**
Update count: **0**

Registration date
2024-02-28, 1402/12/09

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-03-05, 1403/12/15
Expected recruitment end date
2025-11-21, 1404/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the Effect of Active Vision Therapy on visual skills using Vision Therapy System 4 (VTS4) in children with Bilateral Refractive Amblyopia ages 5-13

Public title
Investigation the Effect of Active Vision Therapy Using Vision Therapy System 4 (VTS4) in Bilateral Refractive Amblyopia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Full patient consent to participate in the study The minimum age is 5 and the maximum is 13 years Bilateral refractive amblyopes Astigmatism more than 1.5 diopters and hyperopia more than 3.00 diopters in each eye or a mix hyperopia-stigmatism Maximum vision 20/40 and minimum vision 20/100 in each eye (moderate amblyopia)

Exclusion criteria:
Children who do not cooperate to perform the tests Children who experience diplopia or nausea while using liquid crystal glasses The presence of uncompensated phoria Children who do not have the necessary follow-up for treatment. The existence of pathological and structural problems of the eye History of eye surgeries The presence of nystagmus strabismus, microtropia or eccentric fixation

Age
From **5 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
patient divide in two control and active treatment groups. Block Randomization is used for this. Blocks of couple of four are created in which, randomly, half of the people in each group are placed in one block and the others in the other group. Using blocks of couple of four, we will place 40 people in two control and treatment groups. First, we determine all the four states in which group. We consider the treatment group as A and the control group as B. 1-AABB 2-ABBA 3-ABAB 4-BBAA 5-BABA 6-BAAB Then, we will randomly select 8 blocks of four and write their combination one after the other, in fact, we will sample 8 times from this 6-member society, that is, a random number between 1 and 6 will be selected 8 times. In this way, the type of treatment will be determined for 40 patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
It will be made in a double-blind manner. In order for the researcher not to know whether the examinee is in the active or inactive vision therapy group, vision therapy will be performed by one person and the main researcher will perform other examinations. In order to blind the participants , we will also consider sessions to perform placebo vision therapy exercises in the office for the patching group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti university of medical sciences

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floor. 13, flat A, he central headquarters of the Ministry of Health, Simayr Iran street, Shahrak Ghods, Tehran

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Postal code
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Approval date
2023-11-26, 1402/09/05

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.513

Health conditions studied

1

Description of health condition studied
amblyopia, lazy eye

ICD-10 code
H53.023

ICD-10 code description
Refractive amblyopia, bilateral,

Primary outcomes

1

Description
visual acuity

Timepoint
before and after

Method of measurement
snellen vision chart LCD chart vision (model,

HDC-9000N/PF, made in South Korea) Howitz company

2

Description
stereoacuity
Timepoint
before and after
Method of measurement
Randot &; Vectogram Registered trade marks of Stereo Optical Co., Inc and Stereo Fly Stereotest of Stereo Optical Company Inc

3

Description
contrast sensitivity
Timepoint
before and after
Method of measurement
Freiburg contrast sensitivity test, made in Germany, designed by Michael Bach, 2011 version

4

Description
Infacility of Accommodation
Timepoint
Before and after
Method of measurement
flipper lens and snellen near chart

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:" Patching and Vision therapy exercises in three sessions of 30 minutes a week with the Vision Therapy System version 4 (an American software (HTS Inc., Gold Canyon, AZ, USA))، consisting of a 50-inch monitor, a case, a gamepad and a pair of liquid crystal glasses and patching eye
Category
Rehabilitation

2

Description
"Control group:" 1-2 hours patching each eye every day and placebo training
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Poostchi clinic
Full name of responsible person
Dr Mohammadreza Talennejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
Information about the primary outcome measure can be shared.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
available for people working in academic institutions and people working in businesses can apply to receive it.
Under which criteria data/document could be used
without limitation
From where data/document is obtainable
Saeedeh Hosseinmenni, researcher of the study: s.hoseiny2021@gmail .com
What processes are involved for a request to access data/document
Two months after application
Comments