Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of CAM therapy with passive occlusion therapy in the management of unilateral amblyopia

Protocol summary

Study aim
To compare the effect of Cambridge vision stimulator (CAM) therapy with passive occlusion therapy in the management of unilateral amblyopia.

Design
Clinical trial with control group, with parallel groups, randomized, phase 2 on 100 patients. A flipping-coin is used for randomization.

Settings and conduct
All participants will be recruited from first diagnosed unilateral amblyopic children referred to the eye center for managing amblyopia in Ruaa optometry clinic, Najaf, Iraq. The main provision of the study will be recruiting those patients who have not been previously received any amblyopia treatment modality. We will record the pre-and post-amblyopia treatment data of patients who will have been followed for three months after CAM therapy and passive occlusion therapy. At the first stage, all selected candidates whose amblyopia has not been managed previously will be corrected. The collected data during the baseline and follow-up examination sessions are included demographic characteristics, uncorrected and corrected distance visual acuity (UDVA and CDVA) using a standard Snellen chart within a 6-meter distance, spherical objective cyclo-refraction.

Participants/Inclusion and exclusion criteria
- Inclusion criteria Children between 4-10-year-old; Patients with unilateral functional amblyopia (due to anisometropia and/or strabismus); Patients who will be newly diagnosed with amblyopia and will be received their first management strategy; Patients with CDVA worse than 0.8 (20/25) - Exclusion criteria Patients with organic amblyopia; Presence of systemic diseases affecting ocular anatomy and function; Patients with a history of amblyopia management and strabismus surgery; Children a premature birth

Intervention groups
Amblyopia treatment by painting on CAM device and occlusion therapy group

Main outcome variables
Uncorrected and best-corrected visual acuity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221009056119N1**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **retrospective**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information

Name
Masoud Khorrami Nejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-06, 1401/06/15

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of CAM therapy with passive occlusion therapy in the management of unilateral amblyopia

Public title
Comparison of CAM therapy with occlusion therapy in the unilateral amblyopia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children between 4-10-year-old Patients with unilateral functional amblyopia (due to anisometropia and/or strabismus) Patients who will be newly diagnosed with amblyopia and will be received their first management strategy Patients with CDVA worse than 0.8 (20/25)

Exclusion criteria:
Patients with organic amblyopia Patients with a history of strabismus surgery

Age
From **4 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of simple randomization is flipping a coin

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
Tehran university of medical sciences

Street address
Nursing And Midwifery School, Tehran University Of Medical Science

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2022-08-14, 1401/05/23

Ethics committee reference number
IR.TUMS.FNM.REC.1401.103

Health conditions studied

1

Description of health condition studied
Refractive amblyopia

ICD-10 code
H53.02

ICD-10 code description
Refractive amblyopia

Primary outcomes

1

Description
The amount of uncorrected and best-corrected distance visual acuity

Timepoint
1, 2 and 3 months after amblyopia treatment

Method of measurement
Using E Snellen visual acuity chart

Secondary outcomes

empty

Intervention groups

1

Description
In the CAM procedure, five discs with different spatial frequencies (SF) (2, 6, 15, 20, 30 cycle/degree) will be presented to the patient (30 minutes, twice a week). Plates with SF equal to the two lines better than the measured baseline CDVA will be chosen. Total period of treatment is 3 months.

Category
Treatment - Devices

2

Description
According to the guidelines of Amblyopia Treatment Studies (ATS), the standard occlusion therapy protocols, in the control group, will be as follows: In patients with severe amblyopia (CDVA worse than 20/100 or 0.8 logMAR) will be instructed to patch the non-amblyopic eye 6 hours a day, and patients with moderate amblyopia (CDVA between 20/80-20/40 or 0.3-0.8 logMAR) and mild amblyopia (CDVA between 20/40-20/25 or 0.2-0.3 logMAR) will be instructed to patch the non-amblyopic eye 2 hours a day without any

extra visual training. Total period of treatment is 3 months.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ruaa optometry clinic

Full name of responsible person
Ruaa Abdulrahman

Street address
Ruaa optometry clinic, Najaf, Iraq

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Najaf

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Masoud Khorrami-Nejad

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Tehran, District 12, Enghelab St، Pich-e-Shemiran

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Masoud Khorrami-Nejad

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Optometry

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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
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
Yes - There is 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
Not applicable

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts after the results are published

To whom data/document is available
All pepole

Under which criteria data/document could be used
Comparison of results in other races and countries

From where data/document is obtainable
Address: Tehran, Enghelab St., Pich Shamiran, corner of Safi Alishah St., Faculty of Rehabilitation Postal code: 11489-65111 - PO Box: 11365-1683 Dr. Masoud Khorminejad

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

Comments