Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Cambridge Vision Stimulator (CAM) Therapy with Sham CAM Therapy in Patients with Unilateral Functional Amblyopia: A Randomized Clinical Trial.

Protocol summary

Study aim
Comparison of the Effectiveness of Cambridge Vision Stimulator Therapy, Sham Cambridge Vision Stimulator Therapy, and Occlusion Therapy in Improving Corrected Distance Visual Acuity in Patients with Unilateral Functional Amblyopia

Design
A randomized interventional clinical trial with a parallel design and a total sample size of 132 participants (44 participants in each group)

Settings and conduct
This randomized clinical trial will be conducted at the Department of Optometry, School of Rehabilitation, Tehran University of Medical Sciences. All assessments and interventions will be performed by trained optometrists according to a standardized protocol. (No additional space!)

Participants/Inclusion and exclusion criteria
Participants: Children aged 4–8 years with unilateral functional amblyopia. Inclusion criteria: Age 4–8 years, unilateral functional amblyopia, corrected distance visual acuity worse than 0.1 logMAR in the amblyopic eye, presence of anisometropia, strabismus, or both, no previous amblyopia treatment except refractive correction, cooperation of the child and written informed consent from parents. Exclusion criteria: Organic amblyopia, ocular or systemic diseases affecting vision, history of strabismus surgery or prior amblyopia treatment, poor compliance with optical correction, incomplete therapy sessions, or concurrent amblyopia treatments.

Intervention groups
Cambridge Vision Stimulator Treatment Group: Receiving treatment using the Cambridge Vision Stimulator. Sham Cambridge Vision Stimulator Treatment Group: Receiving sham treatment with the Cambridge Vision Stimulator using gray plates. Occlusion Treatment Group: Receiving occlusion therapy according to standard guidelines

Main outcome variables
Change in corrected distance visual acuity (CDVA) of the amblyopic eye measured using the ETDRS logMAR chart

General information

Reason for update

Acronym
CAM-A Trial

IRCT registration information
IRCT registration number: **IRCT20120723010364N4**
Registration date: **2026-01-13, 1404/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-13, 1404/10/23**
Update count: **0**

Registration date
2026-01-13, 1404/10/23

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Cambridge Vision Stimulator (CAM) Therapy with Sham CAM Therapy in Patients with Unilateral Functional Amblyopia: A Randomized Clinical Trial.

Public title

Comparison of CAM and Sham CAM in Pediatric Unilateral Amblyopia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 4 and 8 years Diagnosis of unilateral functional amblyopia Corrected distance visual acuity (CDVA) worse than 0.1 logMAR in the amblyopic eye Presence of at least one amblyogenic factor including anisometropia, strabismus, or both No previous amblyopia treatment except refractive error correction Full-time use of appropriate optical correction for at least 4 months prior to enrollment Cooperation of the child and parents for examinations and follow-up visits Written informed consent obtained from parents or legal guardians

Exclusion criteria:

Presence of organic amblyopia. History of previous amblyopia treatment other than refractive correction. History of strabismus surgery. Presence of systemic diseases affecting ocular anatomy or visual function. Premature birth. Presence of ocular pathology other than amblyopia.

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

A stratified block randomization method will be used. Participants will be stratified based on type of amblyopia (anisometropia, strabismus, combined) and baseline CDVA severity (mild, moderate, severe). Within each stratum, participants will be randomly assigned to CAM therapy, Sham CAM therapy, or occlusion therapy. The unit of randomization is the individual participant. The random sequence will be generated using statistical software, and group allocation will be implemented through sealed, opaque, sequentially numbered envelopes. Envelopes will be opened only after enrollment to ensure allocation concealment

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and their parents/caregivers will be blinded to the type of assigned intervention. In addition, outcome assessors measuring corrected distance visual acuity will be blinded to group allocation. Although the therapist administering the intervention will be aware of the treatment type, they will not be involved in outcome assessment or data analysis. Therefore, the study is conducted as a double-blind trial.

Placebo

Used

Assignment

Parallel

Other design features

A distinctive feature of this study is the inclusion of a Sham CAM group as a non-pharmacological placebo control, which allows differentiation between the true effect of CAM visual stimulation and the effect of short-term occlusion. In addition, the use of stratified randomization based on amblyopia type and severity ensures balanced groups, and multiple follow-up assessments (at 1, 2, and 4 months) enable evaluation of treatment effects over time

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing and Midwifery and the School of Rehabilitation, Tehran Uni

Street address

Keshavarz Boulevard, Quds Intersection, Central Administration of Tehran University of Medical Sciences

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Approval date

2025-10-22, 1404/07/30

Ethics committee reference number

IR.TUMS.FNM.REC.1404.172

Health conditions studied

1

Description of health condition studied

Unilateral Functional Amblyopia

ICD-10 code

H53.0

ICD-10 code description

Amblyopia ex anopsia

Primary outcomes

1

Description

Change in corrected distance visual acuity (CDVA) of the amblyopic eye, measured using the ETDRS logMAR chart at baseline and at 1, 2, and 4 months after the intervention

Timepoint

The primary outcome will be measured at baseline (before the intervention) and at 1, 2, and 4 months after initiation of the intervention.

Method of measurement

Corrected distance visual acuity is measured using the Early Treatment Diabetic Retinopathy Study distance visual acuity chart, and results are recorded on the logarithm of the minimum angle of resolution scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Sham therapy using the Cambridge Vision Stimulator (CAM) device.Participants in this group view the CAM device displaying uniform gray plates with no spatial patterns. Each treatment session lasts 30 minutes, conducted three times per week for a total duration of 4 weeks (12 sessions in total). Sessions are supervised directly by a trained optometrist in the clinic. During the sessions, the non-amblyopic eye is occluded using a standard eye patch. The device used is the standard model Cambridge Vision Stimulator (manufacturer: Clement Clarke International).

Category

Treatment - Devices

2

Description

Intervention group: Intervention Group 1:Active therapy using the Cambridge Vision Stimulator (CAM) device.Participants in this group view the CAM device displaying rotating sinusoidal grating patterns with various spatial frequencies (2, 6, 15, 20, and 30 cycles per degree). Each treatment session lasts 30 minutes, conducted three times per week for a total duration of 4 weeks (12 sessions in total). Sessions are supervised directly by a trained optometrist in the clinic. During the sessions, the non-amblyopic eye is occluded using a standard eye patch. The device used is the standard model Cambridge Vision Stimulator (manufacturer: Clement Clarke International).

Category

Treatment - Devices

3

Description

Intervention group: Intervention Group 2:Standard occlusion therapy.Participants in this group receive patching of the sound eye according to clinical guidelines based on age and amblyopia severity. Patching duration is determined as follows: Severe amblyopia (CDVA worse than 20/100 or 0.7 logMAR): 6 hours per day Moderate amblyopia (CDVA between 20/80–20/40 or 0.6–0.3 logMAR): 2 hours per day Mild amblyopia (CDVA between 20/40–20/30 or 0.3–0.2 logMAR): 2 hours per day Treatment lasts 4 weeks and is administered at home using a standard optical occlusive eye patch (e.g., Orthoptic Eye Patch) under parental supervision.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Dr. Hesam Hashemian

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Sponsors / Funding sources

1

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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

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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