Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Combined Atropine and Patch Therapies for Amblyopia treatment in Children aged 3-17 years old

Protocol summary

Study aim
To determine the effect of combined treatment with atropine and patching in comparison to patching alone in the treatment of amblyopia in children

Design
In this clinical trial study, after approval of the proposal and obtaining ethics approval from the Shahid Beheshti University of Medical Sciences, children aged 3 to 17 years with strabismus amblyopia or anisometropic amblyopia who either had inadequate response or insufficient compliance with previous patch therapy were divided into two groups. Fifty patients received atropine 1% therapy for 3 months (every night except Fridays and Saturdays), while patch therapy for the healthy eye was only continued in cases where it was already being used. The other 50 patients continued their patch therapy along with atropine treatment. Changes in visual acuity (VA) in the amblyopic eye were assessed at 3 and 6 months. The primary variable was BCVA, and secondary variables included age, cause of amblyopia, prior amblyopia treatment before starting the current therapy, type of refractive error, type of strabismus, and the patients' quality of life, which were reviewed and recorded in both groups.

Settings and conduct
Torfeh ophthalmology training center

Participants/Inclusion and exclusion criteria
Children aged 3 to 17 years with amblyopia due to strabismus, anisometropia, deprivation or combined

Intervention groups
50 patients in case group with atropine and patching 50 patients in control group with patching alone

Main outcome variables
Age Sex Weight Visual acuity correction children life quality adverse effect of treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241003063251N1**
Registration date: **2024-12-09, 1403/09/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-09, 1403/09/19**
Update count: **0**

Registration date
2024-12-09, 1403/09/19

Registrant information

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Maryam Oraee Yazdani
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-05, 1403/09/15

Expected recruitment end date
2025-09-06, 1404/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Combined Atropine and Patch Therapies for Amblyopia treatment in Children aged 3-17 years old

Public title
The effect of atropine drops on the treatment of lazy eye in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children from 3 to 17 years of age referred to the strabismus clinic of Torfeh training center Unilateral amblyopia and refractory to treatment due to strabismus or anisometropia or depreciative or combined Failure to respond to previous patch therapy treatment means failure to improve BCVA at least two lines according to the Snellen chart after patch therapy for at least 6 months.
Exclusion criteria:
Children outside the age range of 3 to 17 years old Non refractory amblyopia
Age
From **3 years** old to **17 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
This study uses a simple randomization approach, dividing patients into two groups.one group(A) receives patch therapy alone, while the other group(B) receives patch therapy along with one drop pf 1% atropine, administered once a day for five days a week (excluding Thursday and Fridays) for 3 months and evaluation is done every three months. if the amblyopia improves and the BCVA of both eyes is equal, atropine is stopped, and patch therapy also gradually decreases and stops. if there is no response after 6 months, the treatment with atropine is stopped, and in patients who have a partial response to the treatment, the treatment with drops continues.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti university of medical science
Street address
Daneshjou Blvd., Velenjak, Shahid beheshti university of medical science
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1985717443
Approval date
2024-07-31, 1403/05/10
Ethics committee reference number
IR.SBMU.MSP.REC.1403.258

Health conditions studied

1

Description of health condition studied
Amblyopia
ICD-10 code
H-52
ICD-10 code description
Disorders of refraction and accommodation

Primary outcomes

1

Description
Corrected vision before treatment and 6 months after treatment
Timepoint
Before starting, 3 months later, 6 months after treatment
Method of measurement
logmar

Secondary outcomes

empty

Intervention groups

1

Description
Treatment group(A): treatment with patching alone
Category
Treatment - Drugs

2

Description
Treatment group(B): treatment with patching and atropine drop
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Torfeh hospital
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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?
No
Title of funding source
No
Proportion provided by this source
1
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

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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