Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Investigating and comparing the effect of 0.05%Atropine with minus lens therapy method on angle and control of deviation in children with intermittent exotropia.

Protocol summary

Study aim

The negative lens, as one of the most effective treatment methods for intermittent exotropia, may increase the risk of myopia. By reviewing the case report articles in the field of myopia control using low-dose atropine, it has been found that it can reduce the amount of exo deviations. Therefore, the aim of this study is to compare the effectiveness of these two methods for treating intermittent exotropia while also providing an alternative method to reduce the risk of myopia progression.

Design

Clinical trial with standard intervention group, two parallel groups, randomized in phase 3 on 42 children, No masking, computer software is used for randomization.

Settings and conduct

Children with intermittent exotropia who visited in Rasool Akram Hospital were randomly assigned to one of the intervention groups. All the variables are checked before, 1 month and 3 months after the intervention. Due to the types of intervention, there is not possible to blind the patients or the examiner.

Participants/Inclusion and exclusion criteria

inclusion criteria: Full term children aged 2 to 8 years with intermittent exotropia. Exclusion criteria: History of drug sensitivity or diseases such as epilepsy, convulsions and asthma, vertical ocular deviation above 5 prism, history of strabismus surgery, amblyopia or Unwillingness to continue examination sessions.

Intervention groups

In the glasses treatment group, the smallest amount of negative lens that leads to deviation control is used. In the drop treatment group, parents are asked to put one drop of 0.05% atropine in each of the child's eyes every day

Main outcome variables

Angle of deviation, control of deviation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058588N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

farzaneh Dehghanian Nasrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating and comparing the effect of 0.05%Atropine with minus lens therapy method on angle and control of deviation in children with intermittent exotropia.

Public title
Investigating and comparing effect of low dose Atropine and minus lens therapy on intermittent exotropia.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Full term children with intermittent exotropia.

Exclusion criteria:
Unilateral or bilateral amblyopia history of epilepsy or seizures and asthma history of drug sensitivity history of strabismus surgery presence of vertical deviation more than 5 prisms unwillingness to continue this study

Age
From **2 years** old to **8 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is done in a simple way with individual units and computer software is used in this randomization. The sequence of randomization is given according to a table in the text of the proposal. To assign labels A and B to the intervention group of low-dose atropine and treatment with negative glasses, a coin toss lottery was used, and group B was determined as the intervention group (use of drops) and group A was determined as the intervention group of using glasses.

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
Ethics committee of Iran University of Medical Sciences

Street address
Hemat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2023-05-27, 1402/03/06

Ethics committee reference number
IR.IUMS.REC.1402.168

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
Angle of deviation, control of deviation

Timepoint
Before, one month and 3 months after intervention

Method of measurement
Angle of deviation: prism bar and cover test. Control of deviation: 3 and 6 scale criteria.

Secondary outcomes

1

Description
Stereopsis

Timepoint
Before, one month and 3 months after intervention

Method of measurement
Stereopsis: Titmus

2

Description
Suppression

Timepoint
Before, one month and 3 months after intervention

Method of measurement
4 dots Worth test

3

Description
Accommodation response

Timepoint
Before, one month and 3 months after intervention

Method of measurement

MEM dynamic retinoscopy

Intervention groups

1

Description

Intervention group: Atropine 0.05% is an anticholinergic drug and the first intervention. In order to process this drop, we dilute 0.5% atropine made by Sina Daru Company 10 times with artificial tears. In fact, 1 ml of this drop is combined with 10 ml of artificial tear drops in a special container and given to patients. Parents are asked to put one drop of 0.05% atropine in each eye every day in the afternoon and within a certain time. Parents are taught how to put drops in each eye.

Category

Treatment - Drugs

2

Description

Intervention group: In the treatment with glasses, it will be prescribed based on the lowest power of the negative lens that will lead to the control and reduction of the angle of the deviation. First, the amount of negative lens power equal to 0.5 diopters is placed in front of the eyes, and if the deviation is still not in the controlled state, the amount of negative lens power is increased with steps of 0.25 diopters until the deviation is controlled. The value of the obtained number is added with the amount of spherical refractive error calculated from cyclorefraction and the final lens power is prescribed. If it is observed in the follow-up sessions that the deviation is not properly controlled, the power of the negative lens is increased.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram hospital

Full name of responsible person
Dr. Mostafa Soltan Sanjari

Street address
Mansouri Street, Sttarkhan Ave

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 1000

Email
Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Esmaeel Ebrahimi

Street address
Rehabilitation school of Iran university of Medical Sciences, Madadkaran St, Madar square, Mirdamad Ave

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rehab@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Farzaneh Dehghanian Nasrabadi

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Optometry

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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
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
The data of the participating in the study can be shared after de-identifying the people, which is provided to the requester through a SPSS file.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Only in order to check the correctness of the data and analyze them, they can be approved by researchers or scientific institutions.

From where data/document is obtainable
Farzaneh Dehghanian Nasrabadi, Mobile number: 0098 9133609451, Gmail: Fdehghanian1991@gmail.com

What processes are involved for a request to access data/document
After sending an e-mail by a researcher or a person from a scientific and university institution to the mentioned e-mail address and after its verification by Mrs. Dehghanian, these data can be obtained.

Comments