Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the Effectiveness of Atropine 0.01% and 0.02% with placebo treatment on Myopia progression Prevention and Probable Side Effects on Children Aged 6-15 Years Old.

Protocol summary

Study aim

to evaluate the efficacy of Atropine 0.01% and 0.02% in controlling the progression of myopia

Design

This is a double-blinded randomized clinical trial. There are one control and two intervention groups. Participants are randomly allocated into each group. Examiner and patients are blinded about type of intervention. Sample size is 45.

Settings and conduct

The study will be conducted at Poostchi ophthalmology clinic, affiliated by Shiraz University of Medical Sciences, Shiraz, Iran. Randomization will be performed by ophthalmologist. The optometrist and the patients will be blind about the type of intervention.

Participants/Inclusion and exclusion criteria

participants are myopic children aged between 6 and 15 years old. inclusion criteria are myopia between -0.50 D and -6.00 D and astigmatism <= -0.75 D. exclusion criteria are myopic children with any ocular diseases such as cataract, glaucoma, uveitis, strabismus, history of trauma, history of any ocular surgery and any systemic diseases.

Intervention groups

Intervention group 1: treatment with atropine 0.01% (hand made compound with artificial tear produced by Sina-darou company) each day, one drop in each eye during a year. Intervention group 2: treatment with atropine 0.02% (hand made compound with artificial tear produced by Sina-darou company) each day, one drop in each eye during a year. Control group: Myopic patients without any pharmaceutical intervention.

Main outcome variables

Myopia , Axial length of the eye

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180216038747N1**
Registration date: **2018-04-17, 1397/01/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-17, 1397/01/28**
Update count: **0**

Registration date

2018-04-17, 1397/01/28

Registrant information

Name

Sahar mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 1230 2830

Email address

mohaghegh_sahar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of Atropine 0.01% and 0.02% with placebo treatment on Myopia progression Prevention and Probable Side Effects on Children Aged 6-15 Years Old.

Public title
Controlling myopia progression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
myopia -0.50 D to -6.00 D Astigmatism <= 0.75 D
Exclusion criteria:
myopic children with any ocular diseases such as cataract, glaucoma, uveitis, strabismus, history of trauma, history of any ocular surgery systemic diseases
Age
From **6 years** old to **15 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Care provider

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are included with simple randomization method, treatment options (atropine 0.01%, 0.02% or no treatment) are written on cards according to sample size, and randomly allocated to each individual.
Blinding (investigator's opinion)
Single blinded
Blinding description
Data are gathered by optometrist, and she is blinded. Ophthalmologist randomly prescribes treatment options.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Poostchi ophthalmology research center, Zand street
City
Shiraz
Province
Fars
Postal code
8784683498
Approval date
2017-10-18, 1396/07/26
Ethics committee reference number
IR.SUMS.REC.1396.118

Health conditions studied

1

Description of health condition studied
myopia
ICD-10 code
H52.1
ICD-10 code description
Myopia

Primary outcomes

1

Description
Myopia
Timepoint
before intervention and 12 months after intervention
Method of measurement
auto-keratorefractometer,

2

Description
Axial length of the eye
Timepoint
before intervention and 12 months after intervention
Method of measurement
Intra-ocular lens bio-meter,(IOL Master)

Secondary outcomes

1

Description
Pupil size
Timepoint
Before intervention and 1 and 12 months after intervention
Method of measurement
Ruler

2

Description
Accommodation amplitude
Timepoint
Before intervention and 1 and 12 months after intervention
Method of measurement
Near visual acuity chart

Intervention groups

1

Description
Intervention group 1: Myopic children who will get atropine 0.01% (hand made, in compination with artificial tear in Sina-darou company) one drop in each eye, every night during a year.
Category
Treatment - Drugs

2

Description
Intervention group 2: Myopic children who will get atropine 0.02% (hand made, in compination with artificial tear in Sina-darou company) one drop in each eye, every night during a year.
Category
Treatment - Drugs

3

Description
Control group: Myopic children who will get artificial tear as placebo each night, one drop in each eye, every night during a year.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Poostchi Ophthalmology Center
Full name of responsible person
Sahar Mohaghegh
Street address
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1237347
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadreza Talebnejad
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Sahar Mohaghegh
Position
student
Latest degree
Master
Other areas of specialty/work
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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
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
Yes - There is a plan to make this available

Title and more details about the data/document
IPD collected for the primary outcome measure only

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
this only available for people working in academic institutions

Under which criteria data/document could be used
...

From where data/document is obtainable
e-mail: mohaghegh_sahar@yahoo.com

What processes are involved for a request to access data/document
after taking permission from mentor data are send via e-mail

Comments