

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 $\leq$ -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

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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 $\leq$ 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

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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 updating data

Contact

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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