

# 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  $\leq$  -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)

##### Phone

+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  $\leq$  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 combination 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 combination 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

Zand blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

1237347

##### Phone

+98 71 3230 2830

##### Email

mohaghegh\_sahar@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mohammadreza Talebnejad

#### Street address

Zand blvd

#### City

Shiraz

#### Province

Fars

#### Postal code

12345667

#### Phone

+98 71 3230 2830

#### Email

mohaghegh\_sahar@yahoo.com

#### 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

Optometry

##### Street address

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##### City

shiraz

##### Province

Fars

##### Postal code

1234567

##### Phone

+98 71 3230 2830

##### Email

mohaghegh\_sahar@yahoo.com

## Person responsible for scientific 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**

**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**

Optometry

**Street address**

Zand blvd

**City**

Shiraz

**Province**

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**Postal code**

123456

**Phone**

+98 71 3230 2830

**Email**

mohaghegh\_sahar@yahoo.com

**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**