

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Aug 2026

### Study of the effect of atropine eye drops with concentration of 0.1%&0.01% and placebo in natural course of myopia progression in Children with 6 to 18 year olds

#### Protocol summary

##### Study aim

Comparison of the effects of 0.1% and 0.01% concentrations of atropine eye drops and placebo on myopic diopter progression in persons with 6 -18 years old

##### Design

Patients (6-18 years old) with diagnosis of myopia (2-6 diopter) with inclusion criteria will be studied. In first phase of study (treatment phase) 93 pateints with 6-18 years old and diagnosis of myopia 2 diopter or more devided in three droups. First group, 31 patients will receive atropine eye drop (0.1%) in each eye every night for 12 months. In second phase atropine will be stopped and and the patients will follow for 6 months. Second group is similar to first group but will receive atropine eye drop 0.01%. Third group (control group) are 31 patients that will treat with Tirlose artificial eye drop in the bottle of atropine. In second phase artificial eye drop will be stopped and and the patients will follow for 6 months

##### Settings and conduct

The study will be done in eye clinic of Amiralmomenin Hospital in Rasht. This study will be double blind for patients and researcher .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) 6-18 age 2) Myopia or astigmatism (2-6 diopter) 3) No amblyopia Exclusion criteria: 1) over 18 and under 6 years old 2) Amblyopia 3) Strabismus

##### Intervention groups

First group, 31 patients will receive atropine eye drop (0.1%) every night for 12 months. In second phase atropine will be stopped and and the patients will follow for 6 months. Second group is similar to first group but will receive atropine eye drop 0.01%.Third group (control group) are 31 patients that will treat with artificial eye drop. In second phase artificial eye drop will be stopped and and the patients will follow for 6 months.

#### Main outcome variables

percent of myopic power and axial length changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100414003714N3**

Registration date: **2018-07-10, 1397/04/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-10, 1397/04/19**

Update count: **0**

##### Registration date

2018-07-10, 1397/04/19

##### Registrant information

##### Name

Abdolreza medghalchi

##### Name of organization / entity

guilan medical science university

##### Country

Iran (Islamic Republic of)

##### Phone

01317756898-2238306-8

##### Email address

rezamed1340@gums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-06-20, 1397/03/30

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study of the effect of atropine eye drops with concentration of 0.1%&0.01% and placebo in natural course of myopia progression in Children with 6 to 18 year olds

**Public title**

Effect of atropine eye drop for inhibition of myopic progression

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

aged 6-18 Myopia astigmatism (2-6 diopter) No amblyopia

**Exclusion criteria:**

Age under 6 and over 18 Amblyopia Strabismus

**Age**

From **6 years** old to **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **31**

More than 1 sample in each individual

Number of samples in each individual: **31**

First group will receive atropin eye drop 0.1%, second group will receive atropin eye drop 0.01% and third group will receive placebo.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random Allocation will be done according block randomization of 16 blocks of 6. Initially this randomization is depended on gradual presentation and put into secured pocket and keep in research center.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Doctor and patients are not aware of dose and kind of eye drops. Only research center staff knows the subject.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committe of Guilan University of Medical Sciences

**Street address**

Eye Research Center, Amiralmomenin Hospital, 17 Shahrivar ST, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

41396-37459

**Approval date**

2018-06-11, 1397/03/21

**Ethics committee reference number**

IR.GUMS.REC.1397.106

**2****Ethics committee****Name of ethics committee**

Guilan university of medical sciences ethics committees

**Street address**

Eye research center,Rasht, 17 shahrivar St, Amiralmomenin Hospital

**City**

Rasht

**Province**

Guilan

**Postal code**

41396-37459

**Approval date**

2018-06-11, 1397/03/21

**Ethics committee reference number**

IR.GUMS.REC.1397.106

**Health conditions studied****1****Description of health condition studied**

Inhibition of myopic progression with using atropine eye drop

**ICD-10 code**

H52.1

**ICD-10 code description**

Myopia

**Primary outcomes****1****Description**

percent of myopic power and axial length changes

**Timepoint**

6 months after discontinuation of atropine 0.1% and

0.01% eye drop and placebo  
**Method of measurement**  
Auto refractometer and ultrasound

## Secondary outcomes

### 1

#### Description

Myopic power and axial length changes 6 months after treatment withdrawal

#### Timepoint

6 months after discontinuation of atropine 0.1% and 0.01% eye drop and

#### Method of measurement

Auto refractometer and ultrasound

## Intervention groups

### 1

#### Description

Intervention group 1: Receive 0.1% atropine eye drops

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group2: Receive 0.01% atropine eye drops

#### Category

Treatment - Drugs

### 3

#### Description

Control group: receive artificial tear eye drop.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amiralmomenin Hospital

##### Full name of responsible person

Abdolreza Medghalchi

##### Street address

Eye Research Center, Amiralmomenin Hospital, 17 Shahrivar St, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41396-37459

##### Phone

+98 13 3323 6886

##### Email

rezamed1340@gums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Guilan University of Medical Sciences

##### Full name of responsible person

Shadmen Nemati

##### Street address

Shahid Siadaty St, Namju St, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41446-66949

##### Phone

+98 13 3333 5820

##### Email

research@gums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Guilan 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

Guilan University of Medical Sciences

##### Full name of responsible person

Abdolreza medghalchi

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Ophthalmology

##### Street address

Eye Research Center, Amiralmomenin Hospital, 17 Shahrivar St, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41396-37459

**Phone**

+98 13 3323 6886

**Email**

rezamed1340@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Abdolreza medghalchi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

Eye Research Center, Amiralmomenin Hospital, 17  
Shahrivar St, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

41396-37459

**Phone**

+98 13 3323 6886

**Fax**

+98 13 1222 7409

**Email**

rezamed1340@gums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Shila Kianmehr

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Health Service Management

**Street address**

Eye Reserch Center, Amiralmomenin Hospital, 17  
Shahrivar St, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

41396-37459

**Phone**

+98 13 3323 6886

**Email**

shila.kianmehr@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available