# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Nov 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

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**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
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**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

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Shadmen Nemati

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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**

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 Aciences

**Full name of responsible person**

Abdolreza medghalchi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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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)**
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