

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 Amiralмомenin 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

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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

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Approval date

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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

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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

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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 Sciences

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**Contact****Name of organization / entity**

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Full name of responsible person

Abdolreza medghalchi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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

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Full name of responsible person

Shila Kianmehr

Position

Researcher

Latest degree

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Other areas of specialty/work

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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