

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Long-term effect of topical Dorzolamide and Latanoprost on Refraction in patients with primary open-angle glaucoma

Protocol summary

Summary

In this clinical trial, two groups of patients with primary open angle glaucoma (intraocular pressure [IOP] between 21 and 30 mm Hg) are included. Each group contains 44 patients who are older than 16 years. Exclusion criteria include the use of topical and systemic carbonic anhydrase inhibitors and IOP > 30 mm Hg. One group will randomly receive 2% dorzolamide eye drops three times a day and the other group will randomly receive 0.005% latanoprost eye drops once a day. Examinations include manifest refraction using an auto-refractometer (average of three readings), best-spectacle corrected visual acuity with full-correcting glasses using Snellen chart, IOP measurements using Goldmann Applanation tonometer, slit lamp biomicroscopy of cornea and anterior chamber, non-dilated funduscopy, and automated perimetry (Humphrey perimetry). Central corneal thickness (CCT), anterior chamber depth (ACD), and lens thickness (LT) will be measured using IOLMaster. The measurements by IOLMaster as well as refraction will be repeated after the instillation of cyclopantolate eye drops. Two weeks after the initiation of anti-glaucoma medications, all above mentioned examinations will be repeated at least 2 hours after the use of drops. To evaluate the long-term effects, these measurements will be performed 6±1 weeks afterwards. The participants will have an access to the examiner whenever they have blurred vision. A statistical analysis will be used to compare the study groups in terms of any significant differences in refraction, CCT, ACD, and LT as well as to find any correlation between the use of each medication and blurred vision.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052813505N1**

Registration date: **2014-09-07, 1393/06/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-07, 1393/06/16

Registrant information

Name

Hossein Mohammad-Rabie

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00982173430- 00982177558081

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-06-21, 1392/03/31

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Long-term effect of topical Dorzolamide and Latanoprost on Refraction in patients with primary open-angle glaucoma

Public title

Effect of topical Dorzolamide and Latanoprost on Refraction

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: all patients with open angle glaucoma; older than 16; with eye pressure of 21 to 30 mm Hg which have not taken any treatment. Exclusion criteria: previous use of systemic or topical dorzolamide; using contact lens since 1 month ago; taking sulfa drug since 1 month ago; lactation; pregnancy (pregnancy reduce eye pressure and increase cornea thickness); cataract; any kind of eye surgery; CD/disc more than 0.8; best visually by less than 20/40 (with using Pin Hole); any neuropathy, any severe damage to visual field; and also any increase in eye pressure more than 30 mm Hg during the study.

Age

From **16 years** old to **149 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Yaman alley, Velenjak av., Chamran subway

City

Tehran

Postal code

1985717443

Approval date

2013-05-19, 1392/02/29

Ethics committee reference number

sbmu.rec.1392.61

Health conditions studied

1

Description of health condition studied

glaucoma

ICD-10 code

H40.1

ICD-10 code description

Primary open-angle glaucoma

Primary outcomes

1

Description

Refraction

Timepoint

2 and 6±1weeks

Method of measurement

Autorefractometr

Secondary outcomes

1

Description

Visual acuity, thickness of lens and cornea and depth of anterior chamber

Timepoint

2 and 6±1weeks

Method of measurement

Visual acuity with Snellen chart, thickness of lens and cornea and depth of anterior chamber by IOL Master

Intervention groups

1

Description

Control: Including patients who will receive 0.005% latanoprost eye drops once a day for 6±1 weeks.

Category

Treatment - Drugs

2

Description

Control: including patients who will receive 2% dorzolamide eye drops three times a day for 6±1 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Basir Eye Center

Full name of responsible person

DR Mohammad-Rabie

Street address

Jamalzadeh Shomalli ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

DR Mohammad-Rabie

Street address

Yaman alley. Velenjak ave. Chamran subway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Moslehi Moghaddam

Position

MSc of Optometry

Other areas of specialty/work

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Person responsible for scientific

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Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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DR Mohammad-Rabie

Position

Associated professor of ophtalmology

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty