

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Intraocular Pressure Lowering Effect of 0.005% Latanoprost With Two Different Dosing Regimen

Protocol summary

Summary

Forty eyes of 20 patients with ocular hypertension (OHT) or early primary open angle glaucoma (POAG) in both eyes, with considering the inclusion and exclusion criteria mentioned before, were prospectively enrolled in this randomized crossover study. At baseline, subjects underwent a comprehensive ophthalmic examination, including best-corrected visual acuity, slit-lamp biomicroscopy, IOP measurement with a calibrated Goldmann applanation tonometer, gonioscopy, dilated fundoscopic examination, and automated perimetry (SITA Standard algorithm with 24-2 test pattern). In eligible patients, the IOP lowering medications, if any, were discontinued before baseline measurement.

Afterwards, patients were randomly treated with once daily dose of latanoprost 0.005% eyedrop at 9 PM in one eye (group 1) and every other day dose in the other eye (group 2) for 1 month. After 1 month, IOP was measured and recorded for 2 consecutive days at the same time points (9 AM, 4PM, 9PM). Then instillation frequency was switched between the two eyes of the same patient, and the IOP was measured 1 month later in exactly the same way as at the end of the first month. By definition, in the first month, group 1 included eyes receiving the once daily dose of latanoprost and group 2 consisted of eyes receiving the every other day regime. Therefore, in the second month, group 1 consisted of eyes receiving medication every other day and group 2 included eyes receiving the once daily dose. The main outcome measures were the mean change in diurnal IOPs in both groups. Any adverse events were recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102265905N1**

Registration date: **2011-04-10, 1390/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-10, 1390/01/21

Registrant information

Name

naveed Nilforushan

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 66509162

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-07-05, 1387/04/15

Expected recruitment end date

2009-04-16, 1388/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intraocular Pressure Lowering Effect of 0.005% Latanoprost With Two Different Dosing Regimen

Public title

Effect of everyother day dosing regimen of latanoprost on intraocular pressure

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria are: Age ≥ 30 years, IOP ≥ 22 and ≤ 32 mmHg without any IOP lowering medication, cup to disc ratio ≤ 0.6 , mean deviation of ≥ -6 decibel in perimetry and open angles on gonioscopy. Patients with a history of prior ocular surgery, uveitis, herpetic keratitis, and allergy to latanoprost are excluded

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Crossroads of Shahid Hemmat & Shahid Chamran
Expressways Tehran- Iran 1449614535

City

Tehran

Postal code

1449614535

Approval date

2008-01-28, 1386/11/08

Ethics committee reference number

113148

Health conditions studied

1

Description of health condition studied

Glaucoma

ICD-10 code

H40.0 , H4

ICD-10 code description

Ocular Hypertension,primary open angle glaucoma

Primary outcomes

1

Description

Intraocular pressure (IOP)

Timepoint

24 hours before instillation of latanoprost, baseline IOP was measured 3 times ,at 9AM,4PM,and 9PM and again after one and two months of drug usage,based on assigned protocol of drug instillation,were measured at the same time points

Method of measurement

Calibrated Goldmann applanation tonometer

Secondary outcomes

1

Description

Side effects related to drug

Timepoint

At each time visit after instillation of drug ,during 2-month period of study

Method of measurement

Anterior segment exam by slit lamp
biomicroscopy,posterior segment exam by funduscopy lenses, visual acuity test by Snellen chart and patients own description of side effects like significant itching,redness and burning sensation

Intervention groups

1

Description

Eyedrop latanoprost 0.005% once daily at 9 PM in one eye (group 1) and every other day dose in the other eye (group 2) at month1.

Category

Treatment - Drugs

2

Description

Eyedrop latanoprost 0.005% once daily at 9 PM in one eye (group 2) and every other day dose in the other eye (group 1) at month 2.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rassoul Akram Hospital

Full name of responsible person

Naveed Nilforushan

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Eye research center,Rassoul Akram Hospital, Tehran
University of Medical Sciences

Full name of responsible person

Mehdi Modarress zadeh

Street address

8th Floor - Rassoul Akram Hospital - Niayesh St. -
Sattarkhan Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Eye research center,Rassoul Akram Hospital, Tehran
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

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University of Medical Sciences

Full name of responsible person

naveed Nilforushan

Position

Associate Professor of Ophthalmology/M.D.

Other areas of specialty/work

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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