Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
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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
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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
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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
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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