

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy and side effects of Latanoprost versus Timolol on decreasing IOP in patients with glaucoma

Protocol summary

Summary

Purpose of this study is comparing efficacy and side effects of Latanoprost versus Timolol on decreasing IOP in patients with open angle glaucoma visiting Imam Hossein Hospital of Shahrood during March 2015-March 2016; and this goal will perform according to sex and age-groups. This study is randomized, single blind, without placebo-controlled group and in one center will perform and patients will not be informed from type of intervention. Samples after the first wash out period (if they used ophthalmic drop) will separate to two groups according to randomized complete block design. Then one group will receive Latanoprost drop and the other will receive Timolol drop. After the second wash out period the other drug will prescribe. During wash out periods Dorzolamide drop will prescribe to control IOP. Inclusion criteria include open angle glaucoma or ocular hypertension and exclusion criteria include IOP>30mmHg and existing any other ocular disorder except glaucoma. Target sample size is 40. Intervention includes measuring IOP by the ophthalmologist with applanation Haag-Streit tonometer. Study will perform during March 2015-March 2016. Outcome of this study will compare efficacy and side effects of two mentioned drugs in decreasing IOP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042021875N1**

Registration date: **2016-09-18, 1395/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-18, 1395/06/28

Registrant information

Name

Negin Ebrahimi

Name of organization / entity

Medical University of Islamic Azad University of Shahrood

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dr Sahebali Manafi (vice chancellor for research and technology of Islamic Azad University of Shahrood)

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and side effects of Latanoprost versus Timolol on decreasing IOP in patients with glaucoma

Public title

Comparison of efficacy of two ophthalmic drops on decreasing intraocular pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of open angle glaucoma

symptoms; ocular hypertension includes patients with increased IOP; glaucomatous cupping (cup to disc ratio between 0.4 - 0.7; disc-cup asymmetry>0.2; notching of the rim; enlargement of the cup; bleeding of the rim of the disc; degeneration of the nerve fiber layer) Exclusion criteria: Secondary causes of increasing IOP; cup to disc ratio>0.7; IOP>30 mmHg in each stage of the disease; existing of any other ocular disorder except glaucoma; corrected vision less than 20/50; bradycardia; asthma; COPD; consumption of any drug affecting IOP for example beta blockers, corticosteroids, carbonic anhydrase inhibitors, nitrates and alpha 2 agonists; discontent of patient.

Age

From **18 years** old to **75 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

Committee on medical ethics of Medical University of Shahrood

Street address

Medical University of Shahrood, Haftom-e-tir Sq

City

Shahrood

Postal code

Approval date

2015-04-08, 1394/01/19

Ethics committee reference number

930/36

Health conditions studied

1

Description of health condition studied

Glaucoma

ICD-10 code

H40, H40.0

ICD-10 code description

Glaucoma, Glaucoma suspect

Primary outcomes

1

Description

Tonometry

Timepoint

Before intervention, if the first wash out period is needed every 2 weeks during 4 weeks, at the end of the first week, the first and third month, every 2 weeks during 4 weeks in the second wash out period and at the end of the first week, the first and third month after the second wash out period

Method of measurement

Applanation Haag-Streit tonometer

Secondary outcomes

1

Description

Refraction

Timepoint

Before intervention, at the end of the third month, at the end of the sixth month

Method of measurement

Refractor

2

Description

Gonioscopy

Timepoint

Before intervention, at the end of the third month, at the end of the sixth month

Method of measurement

Slit lamp

3

Description

Appointment of cup to disc ratio

Timepoint

Before intervention, at the end of the third month, at the end of the sixth month

Method of measurement

Slit lamp

4

Description

Eye irritation

Timepoint

Before intervention, if the first wash out period is needed

every 2 weeks during 4 weeks, at the end of the first week, the first and third month, every 2 weeks during 4 weeks in the second wash out period and at the end of the first week, the first and third month after the second wash out period

Method of measurement

Questionnaire and examination by slit lamp

5

Description

Blurred vision

Timepoint

Before intervention, if the first wash out period is needed every 2 weeks during 4 weeks, at the end of the first week, the first and third month, every 2 weeks during 4 weeks in the second wash out period and at the end of the first week, the first and third month after the second wash out period

Method of measurement

Questionnaire and examination by slit lamp

Intervention groups

1

Description

Intervention group: Latanoprost ophthalmic drop 0.005% dripping one drop in each eye every night for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Timolol ophthalmic drop 0.5% dripping one drop in each eye twice a day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahrood

Full name of responsible person

Negin Ebrahimi

Street address

Imam Hossein Hospital of Shahrood, Tohidi St, Imam Ave

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology of Islamic

Azad University of Shahrood

Full name of responsible person

Dr Sahebali Manafi

Street address

Islamic Azad University of Shahrood, Daneshgah Blvd

City

Shahrood

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research and technology of Islamic Azad University of Shahrood

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

Imam Hossein Hospital of Shahrood

Full name of responsible person

Negin Ebrahimi

Position

Medical student

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