

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of continuation of prostaglandin analogue use on the incidence of Cystoid Macular Edema (CME) following uncomplicated cataract surgery in glaucoma patients

Protocol summary

Study aim

To evaluate the effect of post-operative latanoprost administration on central macular thickness (CMT) after uncomplicated cataract surgery in glaucoma patients

Design

Two-arm parallel group randomized trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site

Settings and conduct

The study was conducted at Farabi Eye Hospital (Tehran University of Medical Sciences, Tehran, Iran). Patients without any risk factor or abnormality such as cystic changes in the macula in pre-op OCT were included for allocation. Patients were allocated into two groups; In the first group, on postoperative day 1, patients continued receiving latanoprost and other antiglaucoma topical agents to control the IOP. In the second group, on postoperative day 1, latanoprost was discontinued, and patients received any other antiglaucoma topical agents to control the IOP. All surgeries and post-operative examinations were done by the same expert cataract surgeon (GH. F.). Patients were aware of the allocation, while surgeon/examiner (GH. F.), outcome assessor/analyst (M.Y.) were masked to the patient allocation which was done by M.M.

Participants/Inclusion and exclusion criteria

Glaucoma patients treating with latanoprost; who need cataract surgery; and had no other risk factors for the development of pseudophakic macular edema; and with no abnormality in pre-operative optical coherence tomography (OCT) were included.

Intervention groups

Patients were allocated into two groups; continue latanoprost and discontinue latanoprost.

Main outcome variables

Main outcome was defined as central macular thickness

(CMT) change from baseline measured by OCT imaging. Secondary outcomes were incidence of clinical cystoid macular edema, incidence of significant increase in CMT, visual acuity, IOP, and number of antiglaucoma medications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081329326N1**

Registration date: **2016-09-11, 1395/06/21**

Registration timing: **prospective**

Last update: **2019-10-15, 1398/07/23**

Update count: **3**

Registration date

2016-09-11, 1395/06/21

Registrant information

Name

Seyed Masoud Mirghorbani

Name of organization / entity

Farabi Eye Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-09-21, 1395/06/31

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

2016-09-21, 1395/06/31

Actual recruitment end date

2018-09-03, 1397/06/12

Trial completion date

2018-09-03, 1397/06/12

Scientific title

Effect of continuation of prostaglandin analogue use on the incidence of Cystoid Macular Edema (CME) following uncomplicated cataract surgery in glaucoma patients

Public title

Effect of Latanaprost eye drop on retina after cataract surgery in glaucoma patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Glaucoma patients with 18 years old or more Treating with topical latanoprost 0.005% eye drop at least for 6 months with or without other antiglaucoma topical agents Who needed cataract surgery (phacoemulsification)

Exclusion criteria:

History of any intraocular surgery, intravitreal injections, or retinal laser History of trauma Non-glaucomatous optic neuropathy High myopia History of diabetic retinopathy, any age-related macular degeneration (AMD), uveitis, retinal detachment (RD), epiretinal membrane (ERM), and retinal vascular disorders An occurrence of CME in the fellow eye following previous cataract surgery Recent history of NSAID therapy (topical or oral) Any abnormality in fundus examination except for glaucomatous changes Any abnormality in pre-operative macular OCT.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **166**

Actual sample size reached: **156**

Randomization (investigator's opinion)

Randomized

Randomization description

A computer-based program (Excel® Microsoft Office software version 2016) to assign our samples to the two groups was used. The randomization used was block permuted randomization with the random block size of 2,4 and 6. The random sequence obtained by a

biostatistician and it was concealed from the research group by coloring the background of cells in Excel datasheet. Whenever each new patient was a candidate for allocation, one author (M.M) uncolored the devoted cell and allocated the patient according to the written number, 1 for continuing and 2 for stop continuing latanoprost.

Blinding (investigator's opinion)

Single blinded

Blinding description

The design of the RCT was single-masked. Patients were aware of the allocation, while surgeon/examiner (GH.F.), outcome assessor/analyst (M.Y.) were masked to the patient allocation which was done by M.M.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

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Farabi Eye Hospital, Qazvin sq, South Kargar st

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Approval date

2016-08-06, 1395/05/16

Ethics committee reference number

IR.TUMS.FARABIH.REC.1395.397

Health conditions studied**1****Description of health condition studied**

Cystoid macular edema

ICD-10 code

H35.8

ICD-10 code description

Other specified retinal disorders

Primary outcomes**1****Description**

Central Macular Thickness

Timepoint

Before intervention, 1 month after intervention and 3 months after intervention

Method of measurement

Using OCT-SD imaging

Secondary outcomes

1

Description

Intraocular pressure

Timepoint

Before intervention, 1 month after intervention and 3 months after intervention

Method of measurement

Goldmann tonometry

2

Description

Visual acuity

Timepoint

Before intervention, 1 month after intervention and 3 months after intervention

Method of measurement

Snellen chart

3

Description

Number of medications needed to control the IOP

Timepoint

Before intervention, 1 month after intervention and 3 months after intervention

Method of measurement

Medical records

4

Description

Incidence of clinical cystoid macular edema

Timepoint

Before intervention, 1 month after intervention and 3 months after intervention

Method of measurement

Clinical Fundus examination

5

Description

Incidence of significant increase in CMT

Timepoint

Before intervention, 1 month after intervention and 3 months after intervention

Method of measurement

Defined as $\geq 50 \mu\text{m}$ compared to the baseline in OCT imaging

Intervention groups

1

Description

Intervention group : In this group, prostaglandin analogue (Latanaprost eye drop) is discontinued immediately after cataract surgery for 3 months and replaced with other antiglaucoma agents to control IOP.

Category

Treatment - Drugs

2

Description

Control group: Prostaglandin analogue (Latanaprost eye drop, one drop before sleep at night) after cataract surgery will be continued.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Hospital

Full name of responsible person

Ghasem Fakhraie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyed Masoud Mirghorbani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ophthalmology

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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

Not published due to Farabi Eye Research department guidelines.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The study protocol and informed consent will be shared privately, but a report of the study will be shared in public. Depending on the request, all data may be shared.

When the data will become available and for how**long**

After completion of the study, for 12 months.

To whom data/document is available

Just for academic researchers.

Under which criteria data/document could be used

Just for scientific and research purposes.

From where data/document is obtainable

Please send an e-mail with relevant content to corresponding author: m-mirghorbani@razi.tums.ac.ir
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What processes are involved for a request to access data/document

Anyone who needs detailed information on study protocol and informed consent can e-mail to the corresponding author and request for the data. The request will be evaluated in a few weeks.

Comments**Trial results****Please tick if results have been published**

Yes

Summary result posting date

2019-10-15, 1398/07/23

Table of baseline comparison**Participant flow diagram****Table of variable outcomes' results****Table of adverse events****First publication date**

2019-10-01, 1398/07/09

Abstract of published paper

Purpose To evaluate the effect of postoperative latanoprost administration on central macular thickness (CMT) after uneventful cataract surgery in glaucoma patients. Setting Farabi Eye Hospital, Tehran, Iran. Design Prospective randomized clinical trial. Methods In this single-masked trial, glaucoma patients treated with latanoprost who had no other risk factor for the development of pseudophakic macular edema were randomly allocated to continuation of latanoprost or discontinuation of the drop after uneventful cataract surgery. At baseline and postoperatively at 1 month and 3 months, patients had complete ocular examinations and CMT measurements using optical coherence tomography. The main outcome measure was the change in the CMT between baseline measurements and postoperative measurements at 1 month and 3 months. Results One hundred fifty-six eyes (latanoprost 76; discontinuation 80) finished the trial. There were no differences in baseline patient demographics or characteristics, including the CMT, between the two groups. There was transient increase in the mean CMT by $12 \mu\text{m} \pm 49$ (SD) in the latanoprost group at 1 month ($P = .03$); however, the value returned to baseline by 3 months ($6 \pm 55 \mu\text{m}$; $P = .27$). The between-group difference in the mean change in the CMT from baseline was $-3.1 \mu\text{m}$ (95% confidence interval [CI], -18.4 to 12.0 ; $P = .68$) after 1 month and $-10.5 \mu\text{m}$ (95% CI, -26.6 to 5.5 ; $P = .19$) after 3 months; the differences were not significant. Conclusion Latanoprost administration after cataract surgery had no measurable effect on macular thickness.