Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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 permutated 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
Street address
Farabi Eye Hospital, Qazvin sq, South Kargar st
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Tehran
Postal code
1336616351
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 ≥ 50 µm 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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Person responsible for scientific inquiries

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Associate Professor (Subspecialty in Glaucoma)
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Person responsible for updating data

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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 Seyed Masoud Mirghorbani Resident of Ophthalmology Farabi Eye Hospital, Qazvin sq, South Kargar st, Tehran +982155400003
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 µm ± 49 (SD) in the latanoprost group at 1 month (P = .03); however, the value returned to baseline by 3 months (6 ± 55 µm; P = .27). The between-group difference in the mean change in the CMT from baseline was −3.1 µm (95% confidence interval [CI], −18.4 to 12.0; P = .68) after 1 month and −10.5 µm (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.