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The effect of two different anesthesia methods used for cataract surgery on the vascular structure of the optic nerve head

Submission date 25/06/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/06/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/06/2026	**Condition category** Eye Diseases	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Retrobulbar anesthesia and topical anesthesia are both commonly used during cataract surgery. Although retrobulbar anesthesia provides excellent pain control and prevents eye movement during surgery, concerns have been raised about its possible effects on the blood supply of the optic nerve. Optical coherence tomography angiography (OCTA) is a non-invasive imaging technique that can measure the tiny blood vessels around the optic nerve. The aim of this study is to compare changes in optic nerve head blood vessel density after cataract surgery in patients receiving retrobulbar anesthesia or topical anesthesia.

Who can participate?
Adults aged 50 years or older with age-related cataract who are scheduled to undergo routine phacoemulsification cataract surgery and are able to provide written informed consent.

What does the study involve?
Participants are randomly allocated to receive either topical anesthesia or retrobulbar anesthesia before cataract surgery. All participants undergo standard phacoemulsification with implantation of a monofocal intraocular lens. Eye examinations, including best-corrected visual acuity, intraocular pressure measurements, slit-lamp examination, and OCTA imaging, are performed one week before surgery and repeated at one week and one month after surgery.

What are the possible benefits and risks of participating?
Participants may not receive any direct medical benefit from taking part in the study. However, the information gained may improve understanding of the effects of different anesthesia techniques on the optic nerve and help guide future cataract surgery practice. The risks associated with participation are the same as those associated with routine cataract surgery and the anesthesia technique used. OCTA is a non-invasive imaging test and does not expose participants to radiation.

Where is the study run from?
Department of Ophthalmology, Gulhane Training and Research Hospital, University of Health Sciences, Ankara, Türkiye.

When is the study starting and how long is it expected to run for?
December 2025 to March 2026.

Who is funding the study?
Investigator initiated and funded. The study receives no external funding.

Who is the main contact?
Dr. Alper Can Yılmaz, dralpercnylmz@icloud.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Alper Can Yilmaz

ORCID ID
https://orcid.org/0000-0001-7554-0843

Contact details
General Tevfik Saglam caddesi, no:1 Etlik/Ankara
Ankara
Türkiye
06010
+90 554 695 53 73
dralpercnylmz@icloud.com

Additional identifiers

Study information

Scientific Title
Quantitative assessment of radial peripapillary capillary plexus vessel density after retrobulbar block in cataract surgery

Study objectives
1. To compare changes in radial peripapillary capillary (RPC) plexus vessel density measured by optical coherence tomography angiography (OCTA) between patients receiving retrobulbar anesthesia and those receiving topical anesthesia for phacoemulsification cataract surgery.

2. To evaluate longitudinal changes in RPC plexus vessel density from baseline to postoperative week 1 and month 1 within each anesthesia group.

3. To compare postoperative clinical outcomes, including best-corrected visual acuity (BCVA), intraocular pressure (IOP), surgical duration, cumulative dissipated energy (CDE), and intraoperative and postoperative complications between the two anesthesia groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/12/2025, University of Health Sciences Scientific Research Ethics Committee (University of Health Sciences, General Tevfik Saglam Caddesi, No. 1, Ankara, 06010, Türkiye; +90 312 304 61 35; gulhane.baek@sbu.edu.tr), ref: 2025-578

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Assessment of the effects of retrobulbar versus topical anesthesia on optic nerve head microvasculature in patients undergoing phacoemulsification cataract surgery.

Interventions
Eligible participants are randomly allocated in a 1:1 ratio to receive either topical anesthesia (active comparator) or retrobulbar anesthesia (experimental intervention) before routine phacoemulsification cataract surgery. Randomization is performed using computer-generated random numbers (Microsoft Excel RAND function) by an independent investigator who is not involved in patient examination, image analysis, or statistical evaluation.

Participants allocated to the topical anesthesia group receive topical 0.5% proparacaine hydrochloride ophthalmic drops immediately before surgery. Participants allocated to the retrobulbar anesthesia group receive an ultrasound-guided retrobulbar injection consisting of 4 mL of a local anesthetic mixture containing 40 mg/2 mL lidocaine and 0.025 mg/2 mL epinephrine after negative aspiration to avoid intravascular administration.

All participants undergo standard phacoemulsification cataract surgery with implantation of a single-piece monofocal intraocular lens in the capsular bag. Optical coherence tomography angiography (OCTA) examinations are performed one week before surgery (baseline) and repeated at postoperative week 1 and month 1. Best-corrected visual acuity, intraocular pressure, and slit-lamp examinations are also performed at each scheduled visit. OCTA images are independently reviewed by two masked graders for image quality and segmentation accuracy before quantitative analysis.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Radial peripapillary capillary (RPC) plexus vessel density measured using optical coherence tomography angiography (OCTA) using the RTVue XR Avanti system (Optovue Inc., Fremont, CA, USA). Vessel density (%) is automatically quantified using the AngioAnalytics™ software at 1 week before surgery, postoperative week 1, and postoperative month 1

Key secondary outcome(s)

Completion date
07/03/2026

Eligibility

Key inclusion criteria
1. Adults aged 50 years or older with age-related cataract scheduled for phacoemulsification surgery
2. Presence of visually significant cataract requiring elective cataract surgery
3. Ability to undergo optical coherence tomography angiography (OCTA) with adequate image quality
4. Ability to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Previous intraocular surgery or ocular trauma
2. Corneal disorders affecting OCTA image quality, including corneal ectatic diseases or significant media opacity
3. Retinal vascular disease, age-related macular degeneration, high or degenerative myopia, or any other retinal pathology that could affect OCTA measurements
4. Glaucomatous or non-glaucomatous optic neuropathy
5. Systemic vascular diseases that could influence ocular microvascular measurements
6. Inability to obtain high-quality OCTA images or to complete the scheduled follow-up examinations

Date of first enrolment
26/12/2025

Date of final enrolment
07/02/2026

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Sağlık Bilimleri Üniversitesi

ROR
https://ror.org/03k7bde87

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data underlying the results reported in this study will be made available upon reasonable request to the corresponding author, dralpercnylmz@icloud.com (Alper Can Yılmaz), subject to institutional policies and ethical approval.

IPD sharing plan summary

Available on request