

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2026	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/06/2026	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 Yilmaz, dralpercnylmz@icloud.com

Contact information

Type(s)

Public, Scientific, Principal investigator

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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