ISRCTN62227730 https://doi.org/10.1186/ISRCTN62227730

A study to find out how well a gentle laser treatment lowers eye pressure in people with glaucoma whose eye drops are no longer working

Submission date
09/04/2026

Recruitment status
No longer recruiting

Registration date
20/04/2026

Overall study status
Completed

Last Edited
20/04/2026

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Glaucoma is a long term eye condition that can damage the optic nerve and lead to irreversible sight loss. This damage is usually linked to high pressure inside the eye. Eye drops are the most common treatment, but for some people they do not lower the pressure enough. This study looked at a laser treatment called micropulse transscleral cyclophotocoagulation, or MP-TSCPC. The main aim was to find out how safe and how effective this treatment is over 6 months in people with two common types of glaucoma, primary open-angle glaucoma and pseudoexfoliative glaucoma. The study also aimed to see whether the results were similar for both types of glaucoma.

Who can participate?
Adults aged between 18 years and 85 years with primary open-angle glaucoma or pseudoexfoliative glaucoma could take part. All participants had eye pressure that remained above their target level despite using the maximum eye drop treatment they could tolerate. People who had previous glaucoma surgery, other types of glaucoma, active eye inflammation, or who could not give informed consent were not included.

What does the study involve?
Participants received a single MP-TSCPC laser treatment to help lower pressure inside the eye. The procedure was done using local anaesthetic around the eye. After treatment, participants continued their usual glaucoma eye drops. They attended follow-up visits over a period of 6 months. At these visits, eye pressure, vision, number of eye drops, and any side effects were recorded.

What are the possible benefits and risks of participating?
The possible benefit of taking part was a reduction in eye pressure, which may help slow further loss of vision. The treatment may also reduce the need for more invasive glaucoma surgery. MP-TSCPC is designed to be gentler than older laser treatments. In this study, no serious

complications were reported. As with any eye procedure, potential risks include temporary discomfort, inflammation, or short term changes in vision.

Where is the study run from?
Special Hospital for Ophthalmology “Clinic Maja” in Niš, Serbia.

When is the study starting and how long is it expected to run for?
October 2018 to April 2022.

Who is funding the study?
Special Hospital for Ophthalmology “Clinic Maja” in Niš, Serbia.

Who is the main contact?
Professor Maja Zivkovic, drzivkovicmaja@gmail.com

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Outcomes of micropulse transscleral cyclophotocoagulation in primary open-angle and pseudoexfoliative glaucoma

Study objectives
To evaluate the 6-month efficacy and safety of micropulse transscleral cyclophotocoagulation (MP-TSCPC) in patients with medically refractory primary open-angle glaucoma and pseudoexfoliative glaucoma, and to compare treatment outcomes between the two glaucoma subtypes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/09/2018, Ethics Committee of the Special Hospital for Ophthalmology "Clinic Maja" (Vizantijski Bulevar 33, Niš, 18000, Serbia; +381 18 533 036; info@klinikamaja.rs), ref: 09/9-2018-1

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Primary open-angle glaucoma, pseudoexfoliative glaucoma

Interventions
Micropulse transscleral cyclophotocoagulation (MP-TSCPC) using the Cyclo G6 system with MicroPulse P3 probe (Iridex Corporation) delivered at 2.0–2.2 W power, 31.3% duty cycle, for 90 seconds per hemisphere, under retrobulbar anesthesia. All patients continued their prescribed topical antiglaucoma medications postoperatively.
Follow up for 180 days.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Intraocular pressure reduction measured using Goldmann applanation tonometry; treatment success defined as IOP reduction ≥20% from baseline without additional surgical intervention at Baseline, 30 days, 90 days, 180 days postoperatively

Key secondary outcome(s))

Completion date
25/04/2022

Eligibility

Key inclusion criteria
1. Patients with primary open-angle glaucoma (POAG) or pseudoexfoliative glaucoma (PEX) refractory to maximally tolerated topical medical therapy
2. Intraocular pressure above target despite maximum tolerated medical treatment
3. Scheduled for micropulse transscleral cyclophotocoagulation (MP-TSCPC) as the primary laser-surgical intervention

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Prior glaucoma surgery or laser treatment
2. Secondary glaucoma of other aetiology
3. Active ocular inflammation
4. Inability to provide informed consent

Date of first enrolment
05/10/2018

Date of final enrolment
25/10/2021

Locations

Countries of recruitment
Serbia

Sponsor information

Organisation
Special Hospital for Ophthalmology "Clinic Maja", Niš, Serbia

Funder(s)

Funder type

Funder Name
Special Hospital for Ophthalmology "Clinic Maja", Niš, Serbia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available