Assessing the Added Value of Adaptive Optics Ophthalmoscopy in Glaucoma Management: A Pilot Study

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1, Quantify and compare vascular and structural parameters obtained from AO-FIO, OCTA, OCT, and CFP in both healthy controls and glaucoma patients; 2, Investigate the correlation between these parameters and assess the additional value of vascular…

Ethical review	Approved WMO
Status	Pending
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON57430

Source
ToetsingOnline

Brief title
AO-FIO in Glaucoma Management

Condition

- Glaucoma and ocular hypertension

Synonym
primary open angle glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: Adaptive Optics, Glaucoma

Outcome measures

Primary outcome

The Inner diameter, outer diameter, parietal thickness, wall cross-sectional

area, and wall-to-lumen ratio (WLR); comparison between glaucoma patients and

healthy controls.

Secondary outcome

n/a

Study description

Background summary

Changes resulting in reduced density and caliber of retinal blood vessels are observed in glaucoma patients. Numerous studies have demonstrated significant reductions in flow density, flow index, and vessel density in the optic nerve head and macula among patients with glaucoma. Additionally, these parameters have shown associations with visual field loss.
The introduction of adaptive optics (AO) in ophthalmic care has resulted in retinal images with unprecedented cellular resolution. AO allows the evaluation of individual retinal structures, including blood vessels.
This pilot study aims to evaluate the parameters of retinal arteries in patients with glaucoma when compared to healthy controls using the rtx1 AO-FIO camera. Also, we want to investigate the associations between these vascular parameters and those retrieved from OCT, OCTA, functional defects in the visual field, and other features important for glaucoma diagnosis such as IOP, CCT, and iridocorneal angle.

Study objective

1, Quantify and compare vascular and structural parameters obtained from AO-FIO, OCTA, OCT, and CFP in both healthy controls and glaucoma patients; 2, Investigate the correlation between these parameters and assess the additional value of vascular parameters obtained from AO-FIO compared to those retrieved

from OCTA, OCT, CFP, and clinical parameters.

Study design

prospective, observational pilot.

Study burden and risks

risks, none. Burden limited to time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Glaucoma patients

- Diagnosis of Primary Open-Angle Glaucoma (POAG) at the Rotterdam Eye Hospital.

Healthy controls
- Age-matched with glaucoma subjects.

Exclusion criteria

A potential glaucoma subject who meets any of the following criteria will be excluded from the study:
1. History of diseases associated to retinal vascular effects (e.g. diabetes, high blood pressure, cardiovascular disease, ocular inflammation, retinal degeneration);
2. Smoking at least weekly within the last 5 years;
3. Any ocular abnormalities likely to interfere with scans (e.g., retinal abnormalities, corneal opacities, moderate to severe cataract, nystagmus);
4. Unable to give informed consent, including age <16 years;
5. Unable to comfortably undergo ocular scans for a total cumulative time of 1 hour (e.g. head and neck mobility issues (including tremors), anxiety, either mentioned or observed, severe eye irritation, severe ptosis).
6. Refractive error larger than 3 diopters.

Additionally, healthy controls will be excluded if they:
1. Do not have a normal IOP range (10-21mmHg);
2. Have fundus abnormalities;
3. Do have a visual field loss;

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-04-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87556.078.24