

The diagnostic ability of angiography in glaucoma

Submission date 02/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/01/2019	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The development of optical coherence tomography (OCTA) has enabled non-invasive measurements of vascular changes in the retinal layers, and this new tool has been increasingly used in retinal diseases and glaucoma. Several previous studies have investigated the vessel density in the peripapillary area or parafoveal region with OCTA in patients with glaucoma. Some of these studies have shown that the abnormal vessel density in OCTA has a significant association with glaucomatous optic nerve damage, although it has been controversial whether these abnormal vascular densities in glaucoma are the primary cause of the disorder or secondary changes due to the disorder.

With the recent developments in OCTA software, it is possible to segment the macular vessel density and to measure the vessel density layer-by-layer. Therefore, in this study, we will analyse the macular vessel density layer-by-layer and compared the diagnostic ability of each for detection of glaucoma.

Who can participate?

Patients with primary open angle glaucoma undergoing treatment with drugs and patients visiting the clinic for regular eye examinations for refractive errors.

What does the study involve?

All participants will be investigated using macular optical coherence tomographic angiography, fundus photography, and 24-2 visual field

What are the possible benefits and risks of participating?

Since this study is observational and evaluating the diagnostic value of OCTA in glaucoma, we expect that there are no benefits or risks to the participants.

Where is the study run from?

Glaucoma clinic in pusan national university Yangsan hospital, Yangsan, South Korea

When is the study starting and how long is it expected to run for?

February 2019 until February 2020

Who is funding the study?
Pusan National University Yangsan Hospital

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
05-2018-145

Study information

Scientific Title
Diagnostic Ability of Macular Vessel Density in the Ganglion Cell–Inner Plexiform Layer on Optical Coherence Tomographic Angiography for Glaucoma

Acronym
OCTAGCIPL

Study objectives
Some previous studies have shown that the abnormal vessel density in OCTA has a significant association with glaucomatous optic nerve damage, although it has been controversial whether these abnormal vascular densities in glaucoma are the primary cause of the disorder or

secondary changes due to the disorder. In addition, with the recent developments in OCTA software, it is possible to segment the macular vessel density and to measure the vessel density layer-by-layer.

We will use optical coherence tomographic angiography to compare the diagnostic ability of measuring abnormal vessel density vs layer-by-layer macular vessel density for detection of glaucoma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Pusan National University Yangsan Hospital, 09/08/2018, ref. 05-2018-145.

Study design

comparative cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied

Glaucoma

Interventions

All participants underwent the following ophthalmic examinations

1. BCVA measurements, slit-lamp examination, gonioscopy, and IOP measurement with the Goldmann applanation tonometer.
2. Red-free fundus photography using a non-mydratic fundus camera (Canon CR-2, Canon, Tokyo, Japan)
3. OCTA measurements using Topcon Atlantis (DRI OCT-1, Topcon, Tokyo, Japan)
4. Automated visual field examination using the Humphrey 740 Visual Field Analyzer (Carl Zeiss Meditec, Dublin, CA, USA) were performed on all subjects.

Glaucoma patients should keep using the glaucoma treatment with topical IOP-lowering agents, and age-matched normal controls who visited our clinic for regular eye examinations for refractive errors.

Intervention Type

Other

Primary outcome measure

The macular vessel density is measured using optical coherence tomographic angiography at the retinal nerve fiber–ganglion cell–inner plexiform layer, retinal nerve fiber–ganglion cell layer, retinal nerve fiber layer, ganglion cell–inner plexiform layer, ganglion cell layer, and inner plexiform layer segments.

Secondary outcome measures

The macular vessel densities in six segments are compared between glaucoma patients and normal controls.

Overall study start date

01/11/2018

Completion date

31/12/2019

Eligibility**Key inclusion criteria**

Patients:

1. Primary open angle glaucoma
2. Undergoing treatment with drugs

Control group:

1. Visited the clinic for regular eye examinations for refractive errors

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

over fifty participants per group

Key exclusion criteria

1. Best-corrected visual acuity less than 20/40
2. Refractive error outside the range of – 6.0 to + 3.0 diopters
3. Astigmatism beyond ± 3.0 diopters
4. Previous ocular trauma
5. Ocular surgery or laser treatment
6. History of ocular or systemic disease that could affect the optic nerve or visual field

Date of first enrolment

01/12/2018

Date of final enrolment

31/01/2019

Locations

Countries of recruitment

Korea, South

Study participating centre

Pusan National University Yangsan Hospital

20-Geumo-ro, Mulgeum-eup, Yangsan, South Korea

Yangsan

Korea, South

50612

Sponsor information

Organisation

Pusan National University Yangsan Hospital

Sponsor details

20-Geumo-ro, Mulgeum-eup, Yangsan, South Korea

Yangsan

Korea, South

50612

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04kkg1090>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Pusan National University Hospital

Alternative Name(s)

PNUH

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Korea, South

Results and Publications

Publication and dissemination plan

Planned publication in the journal Ophthalmology, American Journal of Ophthalmology or JAMA Ophthalmology.

Intention to publish date

01/12/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date