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The diagnostic ability of angiography in glaucoma

Submission date	Recruitment status	[ ] Prospectively registered
02/01/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/01/2019	Eye Diseases	[ ] 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?
Patiens 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?
Jonghoon shin, jjongggal@naver.com

Contact information

Type(s)
Scientific

Contact name
Mr Jonghoon Shin

ORCID ID
http://orcid.org/0000-0003-1721-1253

Contact details
20-Geumo-ro, Mulgeum-eup, Yangsan, South Korea
Yangsan
Korea, South
50612
82-55-360-2595
jjongggal@naver.com

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-mydriatic 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/04kgg1090

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