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The diagnostic ability of angiography in glaucoma

Submission date
02/01/2019

Registration date
23/01/2019

Last Edited
25/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[_] 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?
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Contact information

Type(s)
Scientific

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Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s))
The macular vessel densities in six segments are compared between glaucoma patients and normal controls.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
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Korea, South
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Sponsor information

Organisation
Pusan National University Yangsan Hospital

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

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