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The role of angiography in glaucoma

Submission date
07/03/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
18/02/2022

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The development of optical coherence tomography (OCTA) has enabled non-invasive measurements of vascular (blood vessel) changes in the retinal layers of the eye, 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, and peripapillary vascular density was associated with the severity of visual field damage. However, it remains unknown whether there are significant regional relationships between the peripapillary vascular density and visual field sensitivity. Therefore, the aim of this study is to analyze regional relationships between peripapillary vascular density assessed by optical coherence tomographic angiography and visual field sensitivity in primary open angle glaucoma at different stages and normal eyes. The researchers will investigate relationships between peripapilllary vascular density and visual field sensitivity and compare the diagnostic ability of each for the detection of glaucoma.

Who can participate?
Glaucoma patients and healthy volunteers

What does the study involve?
The study does not involve any interventions, the participants just underwent an eye examination including fundus photo, visual field test, and OCTA.

What are the possible benefits and risks of participating?
As this study doesn't include any interventions no benefits or risks are expected.

When is the study starting and how long is it expected to run for?
July 2018 to December 2019

Who is funding the study?
Pusan National University Hospital (South Korea)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
03-2019-001

Study information

Scientific Title
Regional relationships between peripapillary vascular density assessed by optical coherence tomographic angiography and visual field sensitivity in glaucoma

Acronym
OCTAPVDVF

Study objectives
Some previous studies have shown that reduced peripapillary vascular density was reported in glaucomatous eyes, and peripapillary vascular density was associated with the severity of visual

field damage. However, it remains unknown whether there are significant regional relationships between peripapillary vascular density and visual field sensitivity. Therefore, in this study, the researchers will analyze regional relationships between peripapillary vascular density assessed by optical coherence tomographic angiography and visual field sensitivity in primary open angle glaucoma at different stages and normal eyes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2019, Institutional Review Board of Pusan National University Yangsan Hospital, 20, Geumo-ro, Mulgeum-eup, Yangsan-si, Gyeongsangnam-do, South Korea, Tel: +82 (0) 55 360 3854, Email: pnuyhirb@gmail.com, IRB No. 05-2019-005

Study design
Single-center 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 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
Measured at a single examination:
1. Microvascular images and peripapillary vascular density measured using optical coherence tomographic angiography
2. Visual field sensitivity obtained by automated visual field examination using the Humphrey 740 Visual Field Analyzer

Secondary outcome measures
The diagnostic abilities of the peripapillary vascular density and RNFL thickness for differentiating the control group and glaucoma group (total, mild, moderate-severe subgroups), measured at a single examination

Overall study start date
01/07/2018

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 50 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
01/08/2018

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
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Sponsor information

Organisation
Pusan National University Yangsan Hospital

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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
30/04/2019

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/05/2020	18/02/2022	Yes	No