Autoregulation of retinal blood flow

Gepubliceerd: 01-05-2017 Laatst bijgewerkt: 18-08-2022

Blood pressure status affects the perfusion of the optic nerve head and the retina in subjects with vascular or autonomic dysregulation. Optical Coherence Tomography Angiography is capable of showing the effect.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26189

Bron
Nationaal Trial Register

Aandoening

Hypotension
Orthostatic hypotension
Primary Vascular Dysregulation
Migraine
Hypertension
Glaucoma

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Category 1 funding
Category 3 funding: European committee

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Optic disc capillary density, macula capillary density, and arteriole diameter (assessed by

OCT-A) as a function of blood pressure. The calculation of these parameters is based on custom MATLAB software that will be applied on the images.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The concept of an elevated intraocular pressure (IOP) as the only cause of glaucomatous damage is nowadays considered outdated or at least incomplete. An impaired perfusion of the optic nerve head and retinal nerve fiber layer is presumed to play a role as well. Impaired perfusion has been linked in epidemiological studies to both systemic hypotension and longstanding hypertension. A routine clinical measure of perfusion that allows for a quantitative assessment does not exist. Optical Coherence Tomography Angiography (OCT-A) is a new technique that potentially could uncover impaired perfusion fast and noninvasively.

Objective:

To compare OCT-A findings between non-glaucomatous subjects with low, normal, and high arterial blood pressure.

Population:

Our study will recruit 125 subjects divided equally into 5 categories based on their blood pressure status and the existence of vascular or autonomic dysregulation symptoms.

Description:

All subjects will have one visit to the Laboratory of Experimental Ophthalmology where they will first undergo screening to assess whether they are eligible for the study. This will comprise a questionnaire before the visit, visual acuity and refraction, visual field test, and intraocular pressure (IOP) measurement. Screening will last approximately 20 minutes. If abnormal screening results are obtained, subjects will be referred to their General Practitioner. Even though detection of signs of an eye condition might sometimes affect the subject negatively, an early diagnosis is overall beneficial.

Following screening, 1% tropicamide drops will be applied to both eyes of eligible subjects to

induce mydriasis. During the 20-minute waiting period for pupil dilation, subjects will be asked to fill in one short questionnaire, their Body Mass Index (BMI) will be recorded, and two blood pressure measurements will be taken in sitting position using a standard automatic electronic device.

Fundus images of both eyes will subsequently be recorded as documentation for the retinal and vessel health status. OCT and OCT-A images of the optic disc and the macula will then be obtained from both eyes. Importantly, OCT-A (as well as any OCT module) is an entirely noninvasive technique: it determines blood flow from differences in light reflectance in consecutive images. An image is a matter of <3 seconds for OCT and <10 seconds for OCT-A. For this reason we expect the first part of the protocol to last up to 35 minutes (20 minutes for pupil dilation, 5 minutes for fundus photography and 10 minutes for OCT scans).

The subject will then rest in supine position for 5 minutes before being asked to stand for another 3 minutes. Blood pressure as well as heart rate will be recorded in both positions using the same electronic device as before. OCT-A images will then be immediately obtained from both eyes. The second part of the main protocol is expected to last approximately 20 minutes. Hence, the total duration of the study - including instructions and a short break - is approximately 90 minutes.

Doel van het onderzoek

Blood pressure status affects the perfusion of the optic nerve head and the retina in subjects with vascular or autonomic dysregulation. Optical Coherence Tomography Angiography is capable of showing the effect.

Onderzoeksopzet

n/a

Onderzoeksproduct en/of interventie

n/a

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Any individual between 50 and 65 years old with healthy eyes (only mild refractive abnormalities corrected with glasses are allowed) and good overall health condition, having signed the consent form, and fitting the descriptions:

- Group #1: Symptomatic low blood pressure individuals
Defined as having at least one of: systolic blood pressure below 90 mmHg or diastolic blood pressure below 55 mmHg (without the use of any antihypertensive treatment), and at least one of (Appendix F1c):
a) migraine:

Migraine is defined as already diagnosed, or a score of 4 or 5 in the corresponding section of the questionnaire, according to the Migraine Screening Questionnaire (Positive Predictive Value: 95%, Negative Predictive Value: 94%).14
b) orthostatic hypotension:
Orthostatic hypotension is defined as already diagnosed, or a sustained reduction of systolic blood pressure (SBP) of at least 20 mmHg or diastolic blood pressure (DBP) of 10 mmHg within 3 minutes of standing.15

c) cold intolerance:

Cold intolerance is defined as a score of 30 or more in the corresponding section of the questionnaire.16

- Group #2: Asymptomatic low blood pressure individuals
Defined as having at least one of: systolic blood pressure below 90 mmHg or diastolic blood pressure below 55 mmHg (without the use of any antihypertensive treatment), and none of the symptoms described in Group #1.

- Group #3: Asymptomatic normal blood pressure individuals
Defined as having systolic blood pressure between 110 and 140 mmHg, and diastolic blood pressure between 60 and 85 mmHg (without the use of any antihypertensive treatment), and

none of the symptoms described in Group #1.

- Group #4: Asymptomatic untreated high blood pressure individuals
Defined as having at least one of: systolic blood pressure above 155 mmHg or diastolic blood pressure above 90 mmHg, not using any antihypertensive treatment, and having none of the symptoms described in Group #1.

- Group #5: Treated high blood pressure individuals

Defined as having systolic blood pressure below 125 mmHg and diastolic blood pressure below 75 mmHg, together with a medical history of hypertension and the use of any antihypertensive medication for at least the past 1 year.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•visual acuity less than 0.8

•IOP more than 21 mmHg

•any visual field defect

•sphere of more than (+/-)3D or cylinder of more than (+/-)2D

•positive family history (father, mother, brother or sister) of glaucoma

•OCT-A image quality of 6 or less, or any significant image artifact

•pathological fundus photographs

•diagnosed diabetes mellitus of any type

•medical history of cerebrovascular disease, heart disease or severe anemia

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2017
Aantal proefpersonen:	125
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6103
NTR-old	NTR6444
Ander register	UMCG register: 201700322 : ABR: 61508

Resultaten