Brain Function in Glaucoma

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To examine the presence of structural and functional brain changes in glaucoma patients. Specifically, we are interested in the presence of glaucomatous functional brain changes that are beyond those that can be explained on the basis of propagated...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON46774

Source
ToetsingOnline

Brief title
Brain Function in Glaucoma

Condition

- Glaucoma and ocular hypertension

Synonym
Glaucoma, POAG

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Horizon 2020;project funded by the European union

Intervention

Keyword: Glaucoma, MRI, Neurogeneration, Psychophysics

Outcome measures

Primary outcome

Study 1: Visual motion perception thresholds, eye-movement properties, cortical and subcortical activation (BOLD response) and morphological brain measures;

Studies 2 & 3: cortical and subcortical activation (BOLD response), population Receptive Field (pRF) and cortical Connective Field (CF) estimates, and the functional connectivity of the brain.

Secondary outcome

Difference in primary parameters between groups.

Study description

Background summary

Glaucoma is a chronic ophthalmic pathology, which can lead to irreversible blindness and it is nowadays recognised as a neurodegenerative disease as well. Recent work of our laboratory and of others suggests indeed that glaucoma may affect not only the eyes and the optic nerves, but also the remainder of the visual pathways and visual system in glaucoma patients. Therefore, it appears that glaucoma should not only be considered as *just an eye disease* but also a brain disease. The present study aims to further test the hypothesis of glaucoma also being a brain disease. We will do so by focusing on three aspects: integrity of cortical motion processing (study 1), the functional integrity of the brain *at rest* (study 2) and the plasticity of the visual cortex during *filling-in* (study 3). Using (functional) magnetic resonance imaging (fMRI), this can be done non-invasively in human observers. Because the studies can be conducted in the same patients, and because they share many methodological aspects, they are presented here in a single protocol.

We expect our study to reveal specific glaucomatous deficits in the visual system by probing motion processing and filling-in related activity using psychophysics and functional MRI, as well as by assessing neural activity using resting-state fMRI (rs-fMRI). We expect this knowledge to advance our understanding of the aetiology of glaucoma, providing pointers for developing

new diagnostic tools and more effective rehabilitation methods.

Study objective

To examine the presence of structural and functional brain changes in glaucoma patients. Specifically, we are interested in the presence of glaucomatous functional brain changes that are beyond those that can be explained on the basis of propagated retinal and optic nerve structural damage. Ultimately, such changes may serve as early - independent - markers of glaucoma.

Study design

The study will be an exploratory and observational study; a cross-sectional case-control design with participants with glaucoma (primary open angle (mild, severe), and normal tension (mild, severe)), ocular hypertension (OHT) and controls. Groups will be matched for age and gender. The study consists of two parts: 1) psychophysical experiments (serving study 1), and 2) (f)MRI experiments (serving study 1, 2 and 3). Additionally, for the healthy participants, an ophthalmologic exam will take place prior the start of these two parts. For the glaucoma patients, this information already exists.

Study burden and risks

There are no direct risks associated with the proposed study. The planned ophthalmological examination is akin to the standard examination one receives on a visit to an ophthalmologist, which involves no risks. The MRI scanner that will be used has a magnetic field strength of 3 Tesla, which is a very common field strength used extensively in both clinical practice and research. No side effects have been reported so far from the use of such scanners.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Signed informed consent.
Aged 18 years or older.

Exclusion criteria

Psychiatric disorder, currently and/or in the past
MR- incompatible implants
Claustrophobia
Non-MRI safe tattoos
Use of recreational drugs or medications which may influence neurodegenerative progression
Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	06-06-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	31-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-11-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-07-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	201800265
CCMO	NL65003.042.18