Progression of brain changes in glaucoma

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The primary objective is to study glaucomatous structural brain changes in a longitudinal manner, and how it relates to visual functional loss and glaucomatous retinal changes over time.

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

Summary

ID

NL-OMON44235

Source
ToetsingOnline

Brief title
Progression of brain changes 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,ZonMW,Horizon 2020;project funded by the European union

Intervention

Keyword: Glaucoma, Longitudinal, MRI, Neurodegeneration

Outcome measures

Primary outcome

For T1-weighted MRI scan: GM volume, WM volume, cortical thickness, cortical surface area, and mean curvature.

For Diffusion-weighted MRI scan: Fractional anisotropy (FA) and mean diffusivity (MD).

Secondary outcome

Difference in primary parameters between follow-ups.

Time interval between follow-ups.

Study description

Background summary

Glaucoma is one of the leading causes of irreversible blindness worldwide. The traditional view of glaucoma is that of an eye disease in which an elevation of intraocular pressure (IOP) causes the death of retinal ganglion cells (RGCs) through simple mechanical stress, leading to characteristic visual field (VF) defects. However, between 30-39% of glaucoma patients in Western countries have normal IOP on presentation, a condition referred to as normal-tension glaucoma (NTG). Furthermore, ocular hypertension (OHT) commonly exists as an independent entity in the complete absence of glaucomatous retinal changes.

This lack of consistency in the relationship between IOP and glaucomatous retinal changes challenges our conventional view of glaucoma. One proposed hypothesis is that glaucoma is potentially a neurodegenerative disease of the whole brain, with retinal glaucomatous changes being an extension of that degeneration and not a primary pathology of the retina.

Indeed, numerous MRI studies investigating structural brain changes in glaucoma patients have found evidence of neurodegeneration in both the visual pathway and visual cortex of glaucoma patients. Of course such degeneration could be

attributed to trans-synaptic degeneration and sensory deprivation secondary to glaucomatous retinal damage and its subsequent functional loss. However, more recent studies have also found structural degenerative brain changes beyond the visual system, which cannot be attributed to glaucomatous retinal changes, favoring the hypothesis that glaucoma is a global neurodegenerative disorder of the whole brain.

Although glaucomatous retinal damage over time has been studied extensively using optical coherence tomography (OCT), there is a complete lack of longitudinal studies of glaucomatous brain changes. To the best of our knowledge, all studies of structural brain changes in glaucoma patients have been cross-sectional in nature so far. The proposed study intends to investigate structural brain changes of glaucoma patients using anatomical MRI in a longitudinal manner.

Study objective

The primary objective is to study glaucomatous structural brain changes in a longitudinal manner, and how it relates to visual functional loss and glaucomatous retinal changes over time.

Study design

Historical cohort study

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 scanners which will be used have 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 with 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

- To have participated in one of the relevant past cross-sectional studies conducted in our lab.
- Signed informed consent.

Exclusion criteria

For all subjects:
- Development of ophthalmological or neurological disorders which affect the retina, optic nerve or the brain since the last study
- Refusal to be informed in the event of discovering a brain abnormality in the brain scans
- Use of recreational drugs or medications which may influence neurodegenerative progression
- General contraindications of MRI (including MR-incompatible implants and tattoos, and claustrophobia)
Only for controls:
- Visual acuity lower than 0.8

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:	Pending
Start date (anticipated):	01-08-2017
Enrollment:	84
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-07-2017
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)

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	201700297
CCMO	NL61650.042.17