Pilot study: The retina as a potential window to visualize neuropathology in Alzheimer's disease.

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This pilot study aims to investigate the retina, macula and optic nerve head with Optical Coherence Tomography (OCT) in AD patients in order to identify a neurodegenerative signature of AD in the eye. With Fundus Autofluorescence (FAF), amyloid...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42260

Source
ToetsingOnline

Brief title
Is Alzheimer's disease visible in the eye?

Condition

- Neurological disorders NEC

Synonym
Alzheimer's disease; dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alzheimer's disease, Eye

Outcome measures

Primary outcome

Methods: We will conduct an overal examination of the eye, including vision, eye pressure and fundusphotography. With the use of FDT visual field examination and HRT scan of the optic disc, we aim to exclude glaucoma. Moreover, we conduct OCT and FAF measurements. Prior to measurements with OCT and FAF, pupil dilatation will be performed using tropicamide 0.5%. In total, the examinations will take around 45 minutes.

Primary study parameters/outcome of the study:

(1) Thickness of retina, macula and/or optic disc with OCT

(2) Visualization of amyloid plaques in AD with FAF

Secondary outcome

nvt

Study description

Background summary

The diagnosis of Alzheimer*s disease (AD) is based on clinical criteria supported by either MRI or PET scan or CSF analysis. These ancillary investigations are expensive and/or invasive. The eye is a direct protrusion from the brain and the retina contains neuronal cells. With ophthalmological examination, the retina is easily accessible for investigation. Thus, the retina may be of interest as a *window to the brain* and a potential new diagnostic method for early diagnosis of AD and/or follow-up of possibly

therapeutic agents in the future.

Study objective

This pilot study aims to investigate the retina, macula and optic nerve head with Optical Coherence Tomography (OCT) in AD patients in order to identify a neurodegenerative signature of AD in the eye. With Fundus Autofluorescence (FAF), amyloid plaques in the retina may be visualized. With the use of HRT (Heidelberg Retina Tomograph)-scan and visual field examination with FDT (Frequency Doubling Technology), we aim to exclude glaucoma, since glaucoma can cause decreased retinal thickness (McManus 2013, Mowatt 2008). This pilot study serves three goals: 1. To explore the feasibility and logistics of retina research in AD in the VUMC; 2. To investigate whether OCT and FAF reflect neuropathological changes in AD; 3. To gather data for the calculation of the sample size in a subsequent larger study.

Study design

observational study

Study burden and risks

To conduct reliable ophthalmic examination and to improve the quality of the OCT and FAF, pupil dilatation is necessary with mydriatic drug droplets. Pupil dilatation may cause a modest amount of transient photophobia and blurred vision in some participants, lasting several hours. This may interfere with car driving, so patients are advised not to drive themselves. Adverse ocular or systemic side effects of tropicamide are rare (Vuori et al., 1994; Oqut et al., 1996).
The opthalmic examination, fundus photography and visual field testing are non-invasive examinations without risks. Also OCT, HRT and FAF are non-invasive eye examinations in which light bundles are used to examine the posterior part of the eye. This is harmless and without risks.

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

- Study cases: Patients with early onset (<70 years) AD according to the NINCDS/ADRDA criteria. The patients need to be fully capacitated and able to give informed consent, with a minimum MMSE-score of 17/30 (according to other AD-protocols);- Controls: patients with subjective memory complaints visiting the Alzheimer center, without diagnosis of AD or other neurodegenerative disease.

Exclusion criteria

- Patients with neuro-opthalmological conditions, which may interfere with the OCT and/or FAF data will be excluded (Table 2, Tewarie et al., 2012).
- Patients with progressive dementia, with an MMSE below 17/30 and/or incapacitated and not capable to give informed consent
- Patients with a narrow anterior angle of the eye and/or increased intra-ocular pressure. These patients have a contra-indication to use mydriatic agents.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL49053.029.14