Optical Coherence Tomography to visualize neuropathology in Alzheimer's disease

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This study aims to investigate the retina, macula and optic nerve head with Optical Coherence Tomography (OCT) in a cohort of AD patients in order to identify a neurodegenerative signature of AD consisting of neuroretinal degeneration, vascular...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45755

Source
ToetsingOnline

Brief title
OCT in AD

Condition

- Structural brain disorders

Synonym
Alzheimer's disease and 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, Amyloid-beta, Optical Coherence Tomography, Polarization Sensitive OCT

Outcome measures

Primary outcome

- OCT: thickness of the individual retinal layers, including the choroid, at

the macular region and optic disc

- PS-OCT: presence (and number) of amyloid plaques, thickness and change in

birefringence of RNFL

- Angio-OCT: changes in vessel density around the optic nerve head

Secondary outcome

- Relate the amount of visualized A*-plaques in the retina of AD patients to

other available AD biomarkers (i.e. hippocampal atrophy, CSF biomarkers and

amyloid PET scan).

- Compare findings of standard OCT with available biomarkers (i.e. hippocampal

atrophy, CSF biomarkers and amyloid PET scan)

- Compare findings in vessel density around the optic nerve head to

existing vascular markers (scores on MRI)

Study description

Background summary

The diagnosis of Alzheimer*s disease is based on clinical criteria supported by either MRI or PET scan or CSF analysis. These investigations are expensive and/or invasive. The retina is embryologically derived from the brain and shares many tissue similarities with the cerebral cortex. 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 goal for early diagnosis of AD and/or follow-up of possibly therapeutic agents.

Study objective

This study aims to investigate the retina, macula and optic nerve head with Optical Coherence Tomography (OCT) in a cohort of AD patients in order to identify a neurodegenerative signature of AD consisting of neuroretinal degeneration, vascular changes and visualization amyloid-beta (A*) on the other. In addition to a previous pilot we intend to include a larger cohort of both early onset (EOAD) and late onset AD patients (LOAD), aim to visualize A* with the help of polarization sensitive OCT (PS-OCT) and see if there are vascular changes around the optic nerve head using an angio-OCT. With the use of intra-ocular pressure, a HRT (Heidelberg Retina Tomograph)-scan and FDT (Frequency Doubling Technology), we aim to exclude glaucoma; an important confounder in the relation between neurodegenerative disease and retinal neurodegeneration.

Study design

This is an observational cohort study as an extension of the pilot *The retina as a potential window to visualize neuropathology in Alzheimer's disease*.

Study burden and risks

Patients will have one extra site visit, next tot the regular visits for patient care in the VUmc Alzheimer Center. During this visit, their pupils will be dilated using tropicamide 0.5%, possibly causing temporary blurry vision and mild transient photophobia (lasting several hours). This may interfere with car driving, so patients are advised not to drive themselves. Adverse coular or systemic side effect are very rare. Baseline ophthalmological investigations include OCT, angio-OCT, FDT and HRT. Both these and the newly developed PS-OCT are non-invasive optical eye examinations in which light is used to examine the posterior part of the eye. The used wavelenght and the overall energy level of the light is well below the safety margins and is harmless and without risks.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081HZ

NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Study cases: patients with AD fulfilling the clinical criteria, a MMSE-score of at least 17/30 and proven to be amyloid positive by either decreased CSF A* or a positive amyloid PET scan.
- Controls: patients with subjective memory complaints visiting the Alzheimer center, without diagnosis of AD or other neurodegenerative disease, proven to be amyloid negative by either normal CSF A* or negative amyloid PET scan.

Exclusion criteria

- Subjects with neuro-opthalmological conditions which may interfere with the OCT data
- Subjects with progressive dementia, with an MMSE below 17/30 and/or incapacitated and not capable to give informed consent.

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):	25-10-2016
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Phase-Resolved Optical Coherence Tomography system
Registration:	No

Ethics review

Approved WMO Date:	18-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2017
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	NL57669.029.16