Multimodal Optical-imaging of Retinal manifestations of Alzheimer*s Disease

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To non-invasively explore the retina for (a) potential biomarker(s) using a multimodal retinal imaging platform (i.a. OCT, OCT-A, ultra-widefield fundus photography and metabolic hyperspectral retinal camera).

Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders of the eye
Study type	Observational non invasive

Summary

ID

NL-OMON52275

Source
ToetsingOnline

Brief title
MORAD

Condition

- Neurological disorders of the eye

Synonym
Alzheimer's Disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO,Optos (Nikon)

Intervention

Keyword: Alzheimer's Disease, Biomarker, Imaging, Retina

Outcome measures

Primary outcome

1. Differences between AD patients, patients with SMC and healthy controls for all parameters measured by the different retinal imaging techniques (including OCT, OCT-A, ultra-widefield fundus photography and metabolic hyperspectral retinal camera) at baseline and after two years.

2. Comparison of intra-individual differences (change over time) between AD patients, patients with SMC and healthy controls for all parameters measured by the multimodal retinal imaging platform at baseline and after two years.

Secondary outcome

1. Correlation of the results of the different retinal imaging techniques with established disease biomarkers (CSF concentration of Aβ, Tau, and pTau, hippocampal and cortical atrophy on MRI, and neuropsychological findings).

2. Correlation of possible new AD biomarkers in tear film (in collaboration with Maastricht University Medical Center, MUMC+), to the different retinal imaging

Study description

Background summary

Alzheimer*s disease (AD) is the most common cause of dementia. The optimal window of opportunity for therapeutic strategies lies in the pre-clinical phase of the disease when patients are asymptomatic. Thus, there is an urgent need for tools to diagnose AD in this pre-clinical stage. A potential candidate for

such a diagnostic tool is optical imaging of the retina, as it is non-invasive, patient friendly, rapid, and inexpensive. In this study, we aim to explore differences in the retina of patients with (pre)clinical AD compared to patients without AD using a multimodal retinal imaging platform (i.a. OCT, OCT-A, ultra-widefield fundus photography and metabolic hyperspectral retinal camera), both transversally and longitudinally.

Study objective

To non-invasively explore the retina for (a) potential biomarker(s) using a multimodal retinal imaging platform (i.a. OCT, OCT-A, ultra-widefield fundus photography and metabolic hyperspectral retinal camera).

Study design

This is a transversal and longitudinal, observational, prospective, monocenter study.

Study burden and risks

The study comprises of two visits (with two years in between) that take place at the outpatient ophthalmology department of the Amsterdam University Medical Center (AUMC), location Vrije Universiteit Medical Center (VUmc) with a duration of approximately 1,5-2 hours each, including a general ophthalmological consultation comprising ophthalmological history, intraocular pressure and refraction/visual acuity measurement, tear collection with a Schirmer strip, and non-invasive optical eye examinations with OCT(-A), widefield fundus photography and metabolic hyperspectral retinal camera. For these examinations, pupil dilatation is necessary and will be achieved with a topical mydriatic (Tropicamide 0.5%), which may cause mild transient photophobia and blurred vision (adverse ocular or systemic side effects are very rare). All study procedures are routine medical procedures; therefore, the potential risks are negligible. Benefits include an extensive ophthalmological examination. In case ophthalmological problems are detected, these will be discussed with the involved ophthalmologist and the participant will receive consultation.

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

Age >= 50 years
Mini Mental State Exam (MMSE) greater or equal to 17 (patients who are mentally competent)
Available AD biomarker information

Exclusion criteria

- Pupil dilation inadequate or contraindicated
- Presence of glaucoma, retinal vasculopathy (diabetic, hypertensive)
- Presence of moderate / late-stage age-related macular degeneration
- Media opacities (cataract) precluding good quality imaging
- Refractive error outside the range -6D to +6D
- Inability to obtain good quality images with the OCT(-A), widefield fundus photography and metabolic hyperspectral retinal camera
- Ocular conditions including eye infection, eye inflammation, eye surgery within the
last 28 days or other acute eye conditions.
Presence of other neurodegenerative disease (i.e. other causes of dementia, MS,

Parkinson Disease)

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:	Pending
Start date (anticipated):	01-08-2021
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	16-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-06-2023
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	NL76737.029.21