Tear biomarkers for Alzheimer's disease (AD) screening and diagnosis

Published: 24-04-2020
Last updated: 07-06-2025

To investigate whether tear biomarkers can differentiate between patients and controls, and between patient groups.

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

Summary

ID

NL-OMON56224

Source
ToetsingOnline

Brief title
TearAD

Condition

- Neurological disorders NEC

Synonym
Alzheimer's disease cognitive decline dementia memory problems

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum +
Source(s) of monetary or material Support: Veni

Intervention

- No intervention

Keyword: Alzheimer's disease, biomarkers, dementia, tear fluid

Explanation

N.a.

Outcome measures

Primary outcome

The main study parameter is the difference in level of tear biomarkers (such as
 amyloid-beta and tau) between patients and controls, and between patient
 groups.

Secondary outcome

The correlation between tear biomarkers with CSF and blood biomarkers.
 The correlation between tear biomarkers and other ocular imaging biomarkers

Study description

Background summary

The eyes and the brain are closely connected through the optic nerve (Fig.1A) and both the retina and the central nervous system share a common origin from the developing neural tube. Given this relation, eye problems often reflect brain problems. For example, AD patients suffer from several visual problems including loss of visual acuity, color vision and visual fields and changes in pupillary response, fixation and contrast sensitivity. We hypothesize that tear fluid is a non-invasive source of biomarkers for Alzheimer*s disease (AD).

Study objective

To investigate whether tear biomarkers can differentiate between patients and controls, and between patient groups.

Study design

Case-control observational single-center study

Intervention

Not applicable

Study burden and risks

The expected risks are low because of the non-invasive nature of the study. The study includes one visit of 120 min at which ophthalmic measurements are performed. There are no direct benefits for subjects participating in this study

Contacts

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Trial sites

Trial sites in the Netherlands

Maastricht Universitair Medisch Centrum +
Target size: 200

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Written informed consent obtained and documented
Capable of giving informed consent themselves (MMSE score > 17/30)*

Exclusion criteria

Ocular conditions that could influence tear biochemical parameters (including eye infection, eye inflammation, eye surgery within the last 28 days or other acute eye conditions)
Neurological or systemic chronic conditions known to interfere with retinal thickness (e.g., glaucoma, diabetes mellitus)
Ocular conditions interfering with OCT quality/retinal thickness: e.g. severe cataract, age-related macular degeneration, and glaucoma

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	09-06-2022
Enrollment:	200
Duration:	48 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description
N.a.

Ethics review

Approved WMO Date:	07-08-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-07-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-09-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-03-2025
Application type:	Amendment
Review commission:	METC AZM/UM

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
ClinicalTrials.gov	NCT05655793
CCMO	NL73600.068.20
Research portal	NL-008239