Retinal and cognitive dysfunction in type 2 diabetes: unraveling the common pathways and identification of patients at risk of dementia.

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To determine whether functional and/or structural retinal biomarkers or circulating biomarkers can be used to determine the speed of cognitive decline in people with T2D and MCI and those at higher risk of developing dementia.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55006

Source
ToetsingOnline

Brief title
RECOGNISED

Condition

- Other condition
- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
cognitive impairment, type 2 diabetes

Health condition

cognitieve toestand

Research involving
Human

Sponsors and support

Primary sponsor: Fundació Hospital Universitari Vall D□Hebron - Institut de Recerca, VHIR
Source(s) of monetary or material Support: EU Horizon 2020 programme

Intervention

Keyword: Cognitive dysfunction, Dementia, Retinal dysfunction, Type 2 diabetes

Outcome measures

Primary outcome

Retinal sensitivity assessed by microperimetry

Secondary outcome

a. Retinal variables:

- Retinal neurodysfunction/ neurodegeneration assessed by gaze fixation

(microperimetry), Full-field photopic electriretinogram (ERG) and Spectral

Domain Optical Coherence Tomography (SDOCT).

- Vascular abnormalities assessed by Optical Coherence Tomography Angiography

(OCT-A), and Ultra-wide field Fundus Fluorescein Angiography (FFA).

b. Brain imaging assessed by Magnetic Resonance Imaging (MRI) and 18

Fluoro-2-deoxyglucose-Positron Emission Tomography (18FDG-PET).

c. Circulating biomarkers

d. Other: Geriatric Depression Scale (GDS-15), EQ-5D-3L questionnaire, 25-item

National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25) and

Diabetes Specific Dementia Risk Score (DSDRS).

Study description

Background summary

The retina shares similar embryologic origin, anatomical features and physiological properties with the brain and hence offers a unique and accessible *window* to study the correlates and consequences of subclinical pathology in patients with cognitive impairment. Our hypothesis is that the neurodegeneration of the retina will run in parallel to the neurodegeneration of the brain and, therefore, the signs of neurodysfunction in the retinal assessment will be more evident in those patients with rapid cognitive decline. Microangiopathy will also participate in cognitive decline and its specific role, as well as usefulness of retinal imaging, will be also examined.

Study objective

To determine whether functional and/or structural retinal biomarkers or circulating biomarkers can be used to determine the speed of cognitive decline in people with T2D and MCI and those at higher risk of developing dementia.

Study design

It is a multinational and multicentre prospective, longitudinal cohort observational study.

Study burden and risks

Disadvantages of participating in the study may be
- possible discomfort during the blood test in the studie
- spending more time
- extra hospital visits
- additional tests

Benefit of participating in the study may be
- more testing and research. These can pinpoint any issues that would otherwise have gone unnoticed to more advanced stages.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1. Diagnosis of mild to moderate nonproliferative diabetic retinopathy (ETDRS DR level 20
to 47) confirmed by the reading centre or with no overt retinopathy.
2. Diagnosis of MCI confirmed by a neuropsychological test battery (NTB), CDR and a specialized physician or a neuropsychologist. For the control group the absence of MCI will also be confirmed by a NTB and a specialized physician or a neuropsychologist.

Exclusion criteria

1. Major depression (GDS-15 = 9)
2. Established dementia

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-08-2021
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2022
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
ClinicalTrials.gov	NCT04281186
CCMO	NL74434.018.20