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 are able to differentiate people with mild cognitive impairment (MCI) within the type 2 diabetes (T2D) population (this we will be able to do in the...

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

Summary

ID

NL-OMON54910

Source
ToetsingOnline

Brief title
RECOGNISED

Condition

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

Synonym
cognitive impairment, type 2 diabetes

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Fundació Hospital Universitari Vall D□Hebron, 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

To assess whether retinal sensitivity measured by microperimetry is able to predict cognitive decline and progression to dementia in MCI T2D patients.

Secondary outcome

1) To assess whether retinal sensitivity, measured by microperimetry, can identify individuals with MCI among people with T2D.

2) To assess whether eye fixation, measured by microperimetry, can identify individuals with MCI among people with T2D.

3) To assess whether eye fixation measured by microperimetry is able to predict rapid cognitive decline in T2D patients with MCI.

4) To define a T2D phenotype at high risk of developing dementia based on retinal imaging and functional retinal assessments.

5) To determine whether retinal imaging and functional retinal assessments may identify individuals with MCI among people with T2D.

6) To define a T2D phenotype at high risk to develop cognitive decline and dementia based on retinal imaging plus brain imaging.

7) To define a T2D phenotype at high risk to develop dementia based on retinal

imaging plus brain imaging plus circulating biomarkers.

8) To establish a score to predict cognitive decline or progression from MCI to

dementia based on the variables included in the study.

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 are able to differentiate people with mild cognitive impairment (MCI) within the type 2 diabetes (T2D) population (this we will be able to do in the crosssectional study, and, thus, use retina and/or blood biomarkers as a potential proxy to events taking place in the brain).

Study design

This is a multinational and multicentre cross-sectional 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. Type 2 diabetes
2. 65 years and older
3. Diabetes duration of at least 5 years
4. Mild to moderate non-proliferative diabetic retinopathy (NPDR) or with no overt retinopathy
5. Able to provide informed consent

Exclusion criteria

1. Previous history of stroke or neurodegenerative diseases
2. Severe NPDR, Proliferative DR (PDR), Diabetic Macular Edema (DME) or other eye disorders affecting vision besides these complications of DR

3. Previous laser photocoagulation
4. Other diseases which may induce retinal neurodegeneration (e.g. glaucoma).
5. Subjects with a refractive error = ± 6 D.
6. Media opacities that preclude retinal imaging
7. HbA1C > 10% (86 mmol/mol)
8. Severe systemic illness or personal circumstances that would not make it possible for the patients to fulfil study protocols

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2020
Application type:	First submission
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	NL74408.018.20