Microvascular lesions in the brain: a new perspective on cognitive impairment in type 2 diabetes

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Primary Objective: 1) To charaterize microbleeds and microinfarcts at 7T, and compare their prevalence in people with and without diabetes, with or without cognitive impairmentSecondary Objective(s): 2) To assess the relevance of the lesions in the...

Ethical review	Not approved
Status	Will not start
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON33312

Source
ToetsingOnline

Brief title
Cerebral microvascular lesions in type 2 diabetes

Condition

- Diabetic complications
- Encephalopathies
- Vascular haemorrhagic disorders

Synonym
type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain imaging, cognition, microvascular lesions, Type 2 diabetes

Outcome measures

Primary outcome

The prevalence and total number of microinfarcts and microbleeds at 7T in

relation to DM2 status and cognition.

Secondary outcome

Microvascular lesion load will be related to cognition, conventional MR markers

(atrophy, white matter hyperintensities), vascular and metabolic risk factors,

brain connectivity parameters and cerebral blood flow.

Study description

Background summary

Type 2 diabetes (DM2) is associated with cognitive decrements and an increased risk of dementia. Further insight in the natural history and etiology of these decrements is required to optimize treatment. We aim to identify novel brain imaging correlates of impaired cognition in DM2, which may serve as a surrogate outcome measure in future intervention studies.

Neuropathological studies identify microvascular lesions, i.e. microinfarcts and microbleeds, as important correlates of impaired cognition in older individuals, but these lesions go largely undetected on conventional MR imaging. The introduction of high field strength clinical MR scanners now enables the detection these lesions in vivo. Our hypotheses are that
• microvascular lesions are more common in patients with DM2 and can be detected with high resolution magnetic MR imaging at high field strength (7 Tesla)
• a higher lesion load is associated with impaired cognition, both in older individuals with and without DM2

Study objective

Primary Objective:
1) To charaterize microbleeds and microinfarcts at 7T, and compare their prevalence in people with and without diabetes, with or without cognitive impairment

Secondary Objective(s):
2) To assess the relevance of the lesions in the context of DM2:
- The occurrence of microbleeds and microinfarcts at 7T will be related to other imaging markers of DM2, including WMH volume and diffusion tensor imaging (DTI).
- The occurrence of microbleeds and microinfarcts at 7T will be related to cerebral perfusion and to the presence of metabolic and vascular risk factors

3) To assess the relevance of the lesions in older individuals without DM2

Study design

This is an observational cross-sectional population-based study

Study burden and risks

Approximately 600 eligible individuals will undergo a short telephone interview including a cognitive screening test (10 min). Based on the interview 140 individuals will be visited at home for a detailed neuropsychological assessment (1 hour). From this group, 112 will be selected for a visit to the UMC Utrecht. The visit includes a medical examination (30 min) in which blood is drawn (3x5ml), a 1.5Tesla and 7Tesla MRI scan of 30 minutes each and photograph of the retina. There are no health risks associated with the procedures and techniques used.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100, postbus 85500
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100, postbus 85500
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age between 65 and 80 years
diabetes patients: diagnosed with diabetes for more than 1 year

Exclusion criteria

- Dementia
- TIA or non-invalidating stroke in the past 2 years or any invalidating stroke.
- Other neurological diseases, unrelated to DM2, that are likely to affect cognition, including a history of brain trauma requiring hospitalisation
- Known with or history of psychiatric disorders requiring hospitalisation or >12 months medication use (e.g. schizophrenia , Major depression (DSM IV))
- Contra-indication for 7 Tesla MR imaging (as established by the department)

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:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	140
Type:	Anticipated

Ethics review

Not approved

Date:	26-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL27076.041.09