Functional MRI biomarkers of cognitive decrements in diabetes

Published: 16-05-2012
Last updated: 30-04-2024

The primary objectives are defined according to a hierarchical design: i) to tailor and apply multi-parametric, functional MRI techniques to identify cerebral abnormalities (cerebral biomarkers) in DM2 and MetS; ii) to investigate which cerebral...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON37694

Source
ToetsingOnline

Brief title
Functional MRI in DM2

Condition

- Diabetic complications
- Structural brain disorders

Synonym
brain function, cognition

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: NWO Veni 916.11.059

Intervention

Keyword: Cognition, Diabetes Mellitus type 2, Imaging, Metabolic Syndrome

Outcome measures

Primary outcome

1) To tailor and apply multi-parametric, functional MRI techniques to identify cerebral abnormalities (cerebral biomarkers) in DM2 and MetS.

2) To investigate which cerebral biomarkers are shared and differ between DM2 and MetS.

3) To assess whether these cerebral biomarkers are associated with cognitive decrements in DM2 and MetS.

Secondary outcome

1) To determine whether these neuronal biomarkers are associated with anthropometrical and cardiovascular characteristics.

2) To evaluate which MRI technique is most sensitive for detecting cerebral abnormalities.

Study description

Background summary

Diabetes mellitus type 2 (DM2) is a common chronic metabolic disorder that affects 4.1% of the Dutch population. In addition to vascular disease, DM2 is associated with structural brain changes visible on MRI, accelerated cognitive decline, and dementia in older individuals. The exact pathophysiological mechanisms underlying cognitive decrements in DM2 still remain to be elucidated. The *metabolic syndrome* (MetS), defined as a cluster of cardiovascular risk factors (including obesity, hypertension, and dyslipidemia) is often considered a prediabetic condition. Individuals with MetS display similar cognitive decrements as do DM2 patients, but do not share the severity of brain injury. It has been indicated that in prediabetic MetS, cognitive

problems precede structural brain changes, and that MetS and DM2 affect the brain through a shared mechanism in which vascular co-morbidity is essential.

Study objective

The primary objectives are defined according to a hierarchical design: i) to tailor and apply multi-parametric, functional MRI techniques to identify cerebral abnormalities (cerebral biomarkers) in DM2 and MetS; ii) to investigate which cerebral biomarkers are shared and differ between DM2 and MetS; iii) to assess whether these cerebral biomarkers are associated with cognitive decrements.

Study design

Cross-sectional observational study design

Study burden and risks

The burden for participants is restricted to 30 minutes preparation / aftercare and one MRI scan session of approximately 60 minutes. All the measurements are non-invasive and participants with contra-indications for MRI will be excluded. Therefore the risks associated with participating in this study are negligible. There is a small risk that we detect an incidental finding. In case of significant incidental findings, the general practitioner or relevant specialist will be informed. Consequently, the participant is contacted by telephone within four weeks.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
6202 AZ Maastricht
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General:
subjects aged 40-75 years, subjects enrolled in the existing 'Maastricht Study', Subjects gave written consent to be approached for additional research, subjects belong to the 20% of the worst and 20% of the best performing (as based on neuropsychological cognitive testing) individuals.;Diabetes type 2:
fasting blood glucose >= 7.0 mmol/l, after an oral glucose tolerance test (OGTT) blood glucose >= 11.1 mmol/l or used oral glucose-lowering medication or insulin.;Metabolic Syndrome:
Participants should meet three out of 5 of the following criteria:
1. Waist circumference > 88 cm (women), > 102 cm (men)
2. Triglycerides >= 1.7 mmol/l
3. HDL cholesterol < 1.3 mmol/l (women), < 1.0 mmol/l (men)
4. Blood pressure >= 130/85 mmHg (or medication)
5. Fasting blood glucose >= 6.1 mmol/l, after an OGTT blood glucose >= 7.8 mmol/l;Healthy controls:
Who fulfilled no more that 1 criterium of the metabolic syndrome, no Diabetes type 2.

Exclusion criteria

Contra-indications for MRI examination:
1) pacemaker, 2) neurostimulator, 3) medication pump, 4) cochlear or hearing implant, 5) tattoos or other items that cannot be removed and include metal parts, 6) metal splinter in the eye, 7) pregnancy, 8) claustrophobia, 9) brain vessel clamps, 10) denture, which contains magnets, 11) operations in the past, where metal or synthetic material is used and still were in the body ;Psychiatric comorbidity and inability to perform the functional MRI tests.
Diabetes mellitus type 1 (DM1)
Subjects who are not belonging to the 20% of the worst and 20% of the best performing

individuals
Last visit of the subjects to the M-Study should be less than one year

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:	Recruiting
Start date (anticipated):	24-09-2012
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL38511.068.11