High-field (7T) MRI and genetic biomarkers for neurocognitive impairment in type 2 diabetes melltius

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

Summary

ID

NL-OMON42233

Source
ToetsingOnline

Brief title
7T in type 2 diabetes mellitus

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Structural brain disorders

Synonym
brain structure, cognition

Health condition

Genetic variation

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: STW P11-41

Intervention

Keyword: Cognition, Genetics, Imaging, Type 2 diabetes mellitus

Outcome measures

Primary outcome

MRI Biomarkers of brain alterations, including:

* Quantitative measures (T1/T2* relaxation time maps),

* Cerebral blood flow (arterial spin labeling, ml blood/100 g tissue/min),

* Functional characteristics (in resting state or during a task),

Cognitive functioning z-scores based on different domains:

* Verbal memory

* Attention and flexibility

* Executive functioning

* Fluency

* Psychomotor speed

* General cognitive function

Secondary outcome

Genetic biomarkers, including:

* SNPs

* Heritability

* Anthropometrics, cardiovascular function, mental health, lifestyle and risk

factors obtained from the Maastricht study database.

Study description

Background summary

Type 2 diabetes mellitus (DM2) is a common chronic metabolic disorder characterized by high blood glucose (i.e. hyperglycemia). In addition to vascular disease, DM2 is associated with structural brain changes visible on MRI, accelerated cognitive decline and dementia in older individuals. The progression of normal glucose metabolism to DM2 is a gradual process in which insulin resistance plays a crucial role. Insulin resistance, before the clinical presentation with DM2, is often accompanied by other metabolic and vascular abnormalities which is known as the metabolic syndrome (MetS). Individuals with MetS display similar cognitive decrements as do DM2 patients, but do not share the severity of brain injury. It is known that progression to DM2 results from the interaction of environmental factors with a set of genetic variants. Identifying genetics variants and MRI biomarkers that could predict cognitive decline in DM2 may enable enhancement of DM2-related healthcare by improving treatment and/or (more intensive) precautious strategies.

Study objective

The primary objectives:
1. To tailor and apply high-field multi-parametric and functional MRI techniques to identify cerebral biomarkers in DM2 and MetS patients compared to control subjects.
2. To examine a specific set of genetic hypotheses in DM2 and MetS subjects compared to control subjects
3. To explore the relationship between both cerebral biomarkers and genetic differences to cognitive functioning in DM2 and MetS patients.

The secondary objectives:
1. To determine whether these cerebral biomarkers are associated with anthropometrical and cardiovascular characteristics.
2. To evaluate which MRI technique is most sensitive for detecting cerebral abnormalities

Study design

Cross-sectional observational study design

Study burden and risks

The burden for participants is restricted to 30 minutes preparation/aftercare, one high-field (7T) MRI scan session of approximately 60 minutes. All measurements are non-invasive and participants with contraindications for MRI will be excluded. Therefore the risks associated with participating in this study are negligible. In case of unexpected medical findings, the participant and the general practitioner of the participant will be informed. With regards to the genetic data, results will not be communicated to the subjects as these are considered not relevant for diagnosis or increased risk

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General:
* Aged 40-75
* Enrolled in existing *Maastricht Study* (M-Study)
- Complete dataset available
- Completed all four visits (including 3T MRI scan)
* Gave written informed consent to the M-Study board to be approached for additional research;DM2:
* Fasting blood glucose * 7.0 mmol/l, or
* After an oral glucose tolerance test (OGTT) blood glucose * 11.1 mmol/l or
* Used oral glucose-lowering medication or insulin;MetS:
* Impaired glucose metabolism (IGM) with fasting blood glucose * 6.1 mmol/l or after an OGTT blood glucose * 7.8 mmol/l;In addition, participants should meet two out of 4 of the following criteria [35]:
* Triglycerides * 1.7 mmol/l
* HDL cholesterol < 1.3 mmol/l (women), < 1.0 mmol/l (men)
* Blood pressure * 130/85 mmHg (or medication)
* Waist circumference > 88 cm (women), > 102 cm (men);For age and gender matched controls:
* No IGM and no more than 1 criterion of the metabolic syndrome
* No DM2
* No cognitive impairment (MMSE score > 24)

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 or other disorders likely to impact on informed consent;
* Diabetes mellitus type 1 (DM1).

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:	Recruitment stopped
Start date (anticipated):	13-05-2016
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	26-01-2015
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	NL51219.068.14