Activity of Brown Adipose Tissue during hypoglycaEmia

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To determine the effect of hypoglycaemia on BAT-activity.

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

Summary

ID

NL-OMON36610

Source
ToetsingOnline

Brief title
ABATE

Condition

- Diabetic complications
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes; metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: vanuit eigen stichting

Intervention

Keyword: Brown Adipose Tissue, Thermoregulation, Type 1 Diabetes

Outcome measures

Primary outcome

Change in Standardised Uptake Value (SUV) of the tracer

[18F]-fluorodeoxyglucose (FDG) visualised with positron emission tomography

(PET) in BAT (normoglycaemia vs. hypoglycaemia).

Secondary outcome

Difference between the change in SUV in BAT in the group with healthy

volunteers versus the diabetes patients.

Study description

Background summary

We hypothesise that there is a central mechanism that shuts down energy consumption by brown adipose tissue (BAT) during hypoglycaemia. This could be a mechanism to protect the brain from neuroglycopenia.

Study objective

To determine the effect of hypoglycaemia on BAT-activity.

Study design

Observational design. Two 18F-FDG PET-CT scans per patient will be performed of the upper body half to visualise the activity of BAT.
The first scan will be performed following a hyperinsulinaemic normoglycaemic clamp and the second scan will be performed following a hyperinsulinaemic hypoglycaemic clamp (separated from the first scan by at least 2 weeks).

Intervention

The first scan will be performed following a hyperinsulinaemic normoglycaemic clamp and the second scan will be performed following a hyperinsulinaemic hypoglycaemic clamp (separated from the first scan by at least 2 weeks).

Study burden and risks

Included subjects will visit the AMC hospital on three occasions.
Visit 1: informed consent, medical history, vital signs, explanation of study procedures, laboratory measurements. Total blood drawn: 12.5 ml.
Visit 2: hyperinsulinaemic normoglycaemic clamp and subsequent [18F]FDG-PET scan
Visit 3: hyperinsulinaemic hypoglycaemic clamp and subsequent [18F]FDG-PET scan
At visit 2 and 3: subjects will be asked to come to the AMC in a fasting state.
In total 213.5 ml of blood will be drawn over the study.
Induction of hypoglycaemia can lead to severe hypoglycaemia with coma or seizures. However, this normally does not occur with the arterialized blood glucose values that are reached in this study. In case of adverse sequelae of hypoglycaemia (e.g. coma, epileptic fit), insulin will be discontinued and glucose will be infused until symptoms abate. The patients might develop hypothermia when they stay in a cold room, especially in a situation with hypoglycaemia. We will monitor the patient*s temperature with a tympanic thermometer. In case a patient develops hypothermia the study will be cancelled.The resulting dose from the low-dose CT scan and the injected radioactive tracer is approximately 9.4 mSv. This is classified as an intermediate risk (ICRP62).
There is no direct benefit for the volunteers. The study will provide new physiologic insight in a possible central pathway influencing BAT activity and the effect of diabetes itself on BAT activity and therefore also on temperature regulation and metabolism. This knowledge might be useful in developing strategies to prevent hypoglycaemia and its consequences in insulin treated diabetes. Moreover, insight in the regulatory mechanisms of BAT activity may help to find a way to increase energy expenditure and prevent/treat obesity.

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

Inclusion criteria for healthy volunteers
* Male
* Caucasian race
* 18-50 years old
* BMI 20-28 kg/ m2
* Subjects should be able and willing to give informed consent;Inclusion criteria for type 1 diabetes patients
* Male
* Caucasian race
* Age 18-50 years
* BMI 20-28 kg/ m2
* Type 1 Diabetes Mellitus
* Subjects should be able and willing to give informed consent

Exclusion criteria

Exclusion criteria for healthy volunteers
* Use of prescription medications (beta-adrenoreceptor blockers)
* Cardiac history (previous arrhythmia)
* History of epilepsy
* Acute illness within 3 months before the study
* Significant renal impairment (creatinine clearance <50ml/min)
* Family history of diabetes;Exclusion criteria for type 1 diabetes patients
* Impaired awareness of hypoglycaemia
* Evidence of severe diabetes complications (autonomic neuropathy, macroalbuminuria, proliferative retinopathy)
* Use of beta-adrenoreceptor blockers

* Cardiac history (previous arrhythmia)
* History of epilepsy
* Acute illness within 3 months before the study
* Significant renal impairment (creatinine clearance <50ml/min)

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:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
CCMO	NL34584.018.10