Activity of brown adipose tissue during hypoglycaemia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23492

Source NTR

Brief title ABATE

Health condition

Type 1 Diabetes, Brown Adipose Tissue, Thermoregulation, Type 1 Diabetes, bruin vet, thermoregulatie

Sponsors and support

Primary sponsor: Non-commercial, Stichting Asklepios;J.B.L. HoekstraSource(s) of monetary or material Support: self-financing research

Intervention

Outcome measures

Primary outcome

1. Change in Standardised Uptake Value (SUV) of the tracer [18F]-fluorodeoxyglucose (FDG) visualised with positron emission tomography (PET) in BAT (normoglycaemia vs. hypoglycaemia);

1 - Activity of brown adipose tissue during hypoglycaemia. 11-05-2025

2. Change in Standardised Uptake Value (SUV) of the tracer [18F]-fluorodeoxyglucose (FDG) visualised with positron emission tomography (PET) in BAT (healty volunteers vs. type 1 Diabetes patients).

Secondary outcome

N/A

Study description

Background summary

Brown adipose tissue activity and shivering thermogenesis are considered as two important heat producing mechanisms. Shivering to cold in healthy adults is known to stop when plasma glucose falls below 2.5 mmol/L (insulin induced) and as a result core temperature decreases. We hypothesize that brown adipose tissue activity diminishes during hypoglycaemia.

Study objective

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 design

Scans are performed within a minimum of 2 weeks apart.

Intervention

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).

Contacts

Public Postbus 22660 F. Holleman AMC, Room F4-222 Amsterdam 1100 DD The Netherlands +31 (0)20 5665954 **Scientific** Postbus 22660 F. Holleman AMC, Room F4-222 Amsterdam 1100 DD The Netherlands +31 (0)20 5665954

Eligibility criteria

Inclusion criteria

Inclusion criteria for healthy volunteers:

- 1. Male;
- 2. Caucasian race;
- 3. 18-50 years old;
- 4. BMI 20-28 kg/m2;
- 5. Subjects should be able and willing to give informed consent.

Inclusion criteria for type 1 Diabetes patients:

- 1. Male;
- 2. Caucasian race;
- 3. Age 18-50 years;
- 4. BMI 20-28 kg/m2;
- 5. Type 1 Diabetes Mellitus;
- 6. Subjects should be able and willing to give informed consent.

Exclusion criteria

Exclusion criteria for healthy volunteers:

- 1. Use of prescription medication (beta-adrenoreceptor blockers);
- 2. Cardiac history (previous arrhythmia);
- 3. History of epilepsy;
- 4. Acute illness within 3 months before the study;
- 5. Significant renal impairment (creatinin clearance <50ml/min);
- 6. Family history of diabetes.

Exclusion criteria for type 1 Diabetes patients:

1. Impaired awareness of hypoglycaemia;

2. Evidence of severe diabetes complications (autonomic neuropathy, macroalbuminuria, proliferative retinopathy);

- 3. Use of beta-adrenoreceptor blockers;
- 4. Cardiac history (previous arrhythmia);
- 5. History of epilepsy;
- 6. Acute illness within 3 months before the study;
- 7. Significant renal impairment (creatinin clearance <50ml/min).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial

4 - Activity of brown adipose tissue during hypoglycaemia. 11-05-2025

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2011
Enrollment:	16
Туре:	Actual

Ethics review

Positive opinion		
Date:	09-02-2011	
Application type:	First submission	

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
NTR-new	NL2616
NTR-old	NTR2744
Other	METC AMC : MEC 10/295
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A