# Activity of brown adipose tissue during hypoglycaemia.

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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON23492

**Bron**
NTR

**Verkorte titel**
ABATE

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Non-commercial, Stichting Asklepios;
J.B.L. Hoekstra
**Overige ondersteuning:** self-financing research

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

Scans are performed within a minimum of 2 weeks apart.

### Onderzoeksproduct en/of interventie

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).

# Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-03-2011 |
| Aantal proefpersonen: | 16 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 09-02-2011 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2616 |

| Register | ID |
| --- | --- |
| NTR-old | NTR2744 |
| Ander register | METC AMC : MEC 10/295 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A