Morfologie en functie van de hypothalamus na glucose inname door proefpersonen voor en na het gebruik van een hoogcalorisch dieet gedurende vijf dagen.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21031

Source
NTR

Brief title
N/A

Health condition

diabetes type 2
suikerziekte
ouderdomssuikerziekte
diabetes

Sponsors and support

Primary sponsor: Prof. dr. H. Pijl, internist-endocrinoloog
Source(s) of monetary or material Support: CMSB

Intervention

Outcome measures

Primary outcome

1. FMRI scans of hypothalamus;

2. Polysomnography/MSLT.

Secondary outcome

1. Metabolomics;

2. Inflammatory markers;

3. Oral glucose tolerance test;

4. Gut hormones.

Study description

Background summary

It has long been recognized that the hypothalamus plays a crucial role in metabolism. It is thought that the hypothalamus and brain stem get input from the periphery about the available food sources and that, thereafter, efferent neuroendocrine systems come in action to regulate food intake.

Several groups have focused on the effect of glucose ingestion on blood oxygen level-dependent (BOLD) signals in the hypothalamus (detected by MRI). Although there have been some contradicting papers, most studies found that the BOLD signal is diminished after the ingestion of glucose.

In 1999 Matsuda et al. looked at the effect of glucose ingestion in obese people on BOLD signals in the hypothalamus. The results were compared to healthy controls. It was found that the hypothalamic (paraventricular and ventromedial nuclei) BOLD signal decreases significantly in healthy people compared to obese people.

Similarly, in healthy individuals the BOLD signal diminishes after the ingestion of a glucose

load. In diabetic patients however, the BOLD signal does not decline. This suggests that the hypothalamic response in these patients is altered – which could mean that metabolic and endocrine cues about the metabolic state are erroneously interpreted in diabetic patients.

Therefore, in this study we will evaluate the hypothesis that overfeeding disrupts the hypothalamic response to glucose ingestion in healthy men.

Study objective

Overfeeding disrupts the hypothalamic response to glucose ingestion in healthy men.

Study design

28-02-2009 start of study.

Intervention

High caloric diet during 6 days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy males;

2. Healthy diet;

3. Age 19-29;

4. BMI 19-25 kg/m2;

5. Stable weight for the last 2 years;

6. Caucasian;

7. FPG < 6 mmol/L;

8. Hb > 7.5 mmol/l;

9. No family history of DM2.

Exclusion criteria

1. Use of medication known to affect glucose metabolism (for example prednisone) or lipid metabolism;

2. History of genetic or psychiatric disease (e.g. fragile X syndrome, major depression) that affects the brain;

3. Significant chronic disease;

4. Renal or hepatic disease;

5. Recent weight changes or attempts to loose or gain weight (> 3 kg weight gain or loss, within the last 3 months);

6. Smoking (current);

7. Alcohol consumption of more than 28 units per week at present or in the past;

8. Recent blood donation (within the last 3 months);

9. Recent participation in other research projects (within the last 3 months);
10. Participation in 2 or more projects in one year;

11. Sleep disorders;

12. Contra-indication to MRI scanning:

A. Claustrophobia;

B. Pacemakers and defibrillators;

C. Nerve stimulators;

D. Intracranial clips;

E. Intraorbital or intraocular metallic fragments;

F. Cochlear implants;

E. Ferromagnetic implants.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-02-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-03-2009
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	NL1642
NTR-old	NTR1740
Other	METC LUMC : P08.195
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A