Functional MRI of satiety, the interaction between gastric and oral stimulation and related hormones in healthy men

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Our main goal is to investigate the interaction between food administration, hormone responses and brain responses.

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

Summary

ID

NL-OMON35878

Source
ToetsingOnline

Brief title
Satiety in the human brain

Condition

- Other condition

Synonym
No specific disease

Health condition

geen aandoening; Gaat om centrale regulatie van eetlust

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO-STW

Intervention

Keyword: fMRI, hormones, satiety

Outcome measures

Primary outcome

1) Brain activation associated with the satiation process.

2) Fasting serum concentrations of hormones involved in the satiation process.

3) Measures of subjective ratings of hunger and fullness.

Secondary outcome

1) Subjective ratings of the desire to eat.

2) Subjective ratings of anxiety.

3) Energy intake (kJ) from the breakfast.

Study description

Background summary

The amount and kind of food which are ingested influences the regulation of meal size. Neural signals from the gastrointestinal tract travel via the vagus nerve to the brain stem and thalamus, which projects to the rest of the brain, in particular the hypothalamus, amygdala and primary sensory cortices. In studies, in which the stomach was distended with a gastric balloon, activation was observed in the insula, amygdala, posterior insula, left inferior frontal gyrus and anterior cingulate cortex (Wang et al 2007; Stephan et al 2003). So far, no study has examined the effects of ingestion or infusion of a food in the stomach on the brain. In addition to neural signals, hormonal signals are important for meal termination. Hormones like insulin, ghrelin and CCK interact with gastric as well as sensory signals in the process of satiation, which ultimately leads to meal termination.

Study objective

Our main goal is to investigate the interaction between food administration, hormone responses and brain responses.

Study design

A randomized crossover intervention study

Intervention

Subjects will undergo a MRI scan (3 times). They will consume 500ml of chocolate milk (twice oral, once only gastric load) and once 500ml of water with an thinking agent (guarum). An naso-gastric tube will be placed 4 times. An IV will be placed during all MRI-scans (3 times total), and blood will be drawn 8 times during one session. A breakfast will be consumed three times (after every frmi session), it will consist of bread with toppings.

Study burden and risks

The experiment is non-therapeutic to the subjects and consists of one trainings-session and three study days. The risk associated with participation is negligible and the burden can be considered as low.
Although subjects will be screened for claustrophobia prior to participation in this study, occasionally people experience some claustrophobia*like symptoms when they enter the MRI scanner. Subjects will be informed beforehand about the details of the scanning procedure to ensure that this potential problem is minimized.
Subjects might perceive the drawing of the blood sample as an uncomfortable procedure. To minimize the discomfort, blood sampling will be performed by an experienced nurse, who will be present during the entire study session.
Ingestion of a naso-gastric tube has been considered a low risk; it can be experienced as uncomfortable when ingested and when removed. A subject can have the feeling he has to vomit or a bleeding noose can appear. In rare cases an inflammation in the larynx can occur. In some cases the tube can be placed in the bronchus; this has serious consequences when food will be ingested in the bronchus, which can lead to pneumonia. This can easily be tested by a nurse, and is part of the procedure when placing the tube ("maag-sonde protocol UMC Utrecht"). If a nurse is not sure if the gastric tube is placed right, the food ingestion will not be started. An experienced/qualified nurse will be there to assist during the whole procedure.
There is a small chance that aspiration occurs during the scan. A researcher will be next to the subject the whole experiment to help immediately if this occurs.

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

Men, right-handed, normal weight (BMI between 20-25 kg/m2), age between 18 and 35 years, the willingness to be informed about possible brain abnormalities (incidental findings with MRI)

Exclusion criteria

Not removable metal in body, smoking, excessive alcohol use, diet, medication use (different then paracetamol), claustrophobic.

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2011
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	20-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL35991.041.11