Diurnal and segmental variation in glucose sensing: effects on homeostasis, satiety and energy intake in healthy volunteers

Published: 19-06-2008
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32158

Source
ToetsingOnline

Brief title
Diurnal and segmental variation in glucose sensing

Condition

- Other condition

Synonym
obesity

Health condition

overgewicht

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: food intake, glucose sensing, satiety, small intestine

Outcome measures

Primary outcome

Endpoints of the research are differences in satiety, food intake, and changes

in hormone concentrations between the conditions.

Secondary outcome

Differences between conditions in thirst or nausea.

Study description

Background summary

Overweight is a big and still growing health-related problem.
For many years reserach has been conducted to gain insight into the effects of specific nutrients that may influence hunger related feelings and food intake. The small intestine has proven to be of great importance for the satiating effects of nutrients. Recent findings showed that infusion of fat in the small intestine lowers feelings of hunger and lowers energy intake. Little is known about the effects of carbohydrates (glucose) on the small intestine. It is known that the human body reacts differently to an oral glucose load in the morning compared to an oral glucose load in the evening. Possibly these differences can be partially explained by different effects of glucose on the small intestine.

Study objective

The aim of this research is to determine the effect of glucose in the small intestine on the secretion of hormones, appetite related feelings and food intake, and whether these effects differ between time of day (morning vs

evening) and segment of the small intestine (duodenum vs ileum).

Study design

Both studies will have a randomised dubbelblind crossover design with 3 conditions. The randomisation of the conditions will be done digitally.

Intervention

The subjects receive in the duodenal as well as in the ileal study:
- an oral glucose drink in the morning and in the evening
- an infusion with glucose in the duodenum or ileum, in the morning and in the evening
- an infusion with saline in the duodenum or ileum, in the morning and in the evening

Study burden and risks

This research includes little risks for the subjects. The insertion of the catheter via the nose is a routinely used technique at the Academical Hospital Maastricht, and is at this moment the only technique to infuse glucose in a specific part of the small intestine. The information obtained from this protocol is, however, of great importance for research on the effects of nutrients in the small intestine.

Contacts

Public
Universiteit Maastricht

postbus 616
6200MD Maastricht
Nederland
Scientific
Universiteit Maastricht

postbus 616
6200MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male or female, aged 18-55 years and a Body Mass Index (BMI) of 18-29 kg/m2

Exclusion criteria

Evidence of severe diseases, allergy, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol. Gastrointestinal or hepatic disorders influencing gastrointestinal absorption or transit. Use of psychotropic drugs. Alcohol in excess of 21 units/week for males and 14 units/week for females. Concomitant medication that can increase gastric pH, or alter gastric emptying, or alter intestinal transit, or influence satiety/energy intake. Pregnancy, lactation, wish to become pregnant during study, or having a positive pregnancy test at inclusion. Reported unexplained weight loss/gain of more than 2 kg in the month before the study enrollment. Score > 9 on Factor 1 (dietary restrained) of the Dutch translation of the Three Factor eating Questionnaire (TFEQ). Blood donations less than three months previous to study enrollment. One or more of the following dietary habits: medically prescribed diets, weight reduction diets, or vegetarian/macrobiotic/biologically dynamic food habits. Reported working on late/night shifts.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-05-2008
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-06-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22782.068.08