The effect of food stimuli on the calorie restriction response in healthy subjects

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To examine the effects of odors and / or visual stimuli of food in subjects after 56h of starvation on:-Endocrine parameters-Metabolic parameters-Anthropometric parameters-Autonomic nervous system parameters-Hypothalamic function

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

Summary

ID

NL-OMON32066

Source
ToetsingOnline

Brief title
calorie restriction response and food stimuli

Condition

- Other condition
- Hypothalamus and pituitary gland disorders
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
age-related diseases, diseases of the elderly

Health condition

ouderdomsziekten en verouderingsproces

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: calorie restriction response, food stimuli, hypothalamic response, metabolic reponse

Outcome measures

Primary outcome

-Fasting endocrine and metabolic serum values

-Insulin sensitivity measured by oral glucose tolerance test (OGTT) (area under

the curve (AUC) of insulin, C-peptide, free fatty acid (FFA) and glucose)

-Glucose and FFA oxidation as determined by indirect calorimetry

-Hypothalamic response to oral glucose load as measured by fMRI (functional

magnetic resonance imaging)

-Anthropometric measurements (weight, waist and hip ratio (WHR), blood

pressure, bioelectrical impedance analysis (BIA))

Secondary outcome

none

Study description

Background summary

Calorie restriction (CR) can extend the lifespan and delay the onset of age-related diseases of ad libitum fed organisms ranging from yeast to mammals. In CR humans, promising results have been obtained. CR humans have favorable risk factors for age-related diseases such as diabetes and cardiovascular disease. In addition, CR humans and long-lived CR rodents have a strong overlap in the physiological changes induced by the energy deficit. This so-called CR

response is characterized by a unique endocrine and metabolic status that has been proven to mediate, at least parts of, the beneficial effects of CR.
Several studies have indicated that the brain is involved in mediating CR longevity in diverging species. Specifically, neuronal energy-sensing has been shown to be crucial for the retardation of aging by CR. Energy-sensing in the brain depends on internal cues (glucose, insulin, leptin), but is also affected by hedonic cues such as food-related stimuli. As the human hypothalamus plays a central role in both energy metabolism and modulation of the endocrine system, it might very well be the brain structure to elicit the human CR response.
The CR response of short-term CR and long-term CR seems to the same. Therefore, studying short-term CR interventions can be used as a model to learn more about the mechanisms of CR longevity.
In this protocol we want to investigate the role of energy sensing in the brain on the CR response in humans by means of a 56 hour fasting period with or without food-stimuli. Furthermore, we want to link the results to hypothalamic function by neuro-imaging the hypothalamus during an oral glucose tolerance test.

Study objective

To examine the effects of odors and / or visual stimuli of food in subjects after 56h of starvation on:
-Endocrine parameters
-Metabolic parameters
-Anthropometric parameters
-Autonomic nervous system parameters
-Hypothalamic function

Study design

Randomized cross-over controlled intervention study

Intervention

56h fasting with and without food stimuli

Study burden and risks

The burden of 56 hour fasting en admission will logically be a feeling of hunger. A healthy person will have no health risk of this intervention. The collection of blood and fMRI will not lead to any noteworthy burden or risk except for some dizziness caused by the fMRI scan.

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

-Caucasian male volunteers
-Age > 18 years and < 70 years
-Body mass index (BMI) > 20 kg/m2 and < 25 kg/m2
-Fasting serum glucose < 6.1 mmol/L

Exclusion criteria

-Any significant chronic or hereditary disease (including renal, hepatic or endocrine disease)
-Any significant abnormal laboratory results found during the medical screening procedure
-Any use of medication (except for NSAID)
-Anosmia or any other (acquired) loss of olfaction (ea. rhinitis)

-Recent weight changes or attempts to loose weight (> 3 kg weight gain or loss, within the last 3 months)
-Difficulties to insert an intravenous catheter
-Smoking
-MRI contraindications
-Recent blood donation (within the last 3 months)
-Recent participation in other research projects (within the last 3 months), participation in 2 or more projects in one year

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL21132.058.07