Effects of FASTING duration on cerebral serotonin and dopamine transporter availability in lean and obese subjects

Published: 11-01-2017
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To investigate the effect of fasting duration on cerebral SERT and DAT availability.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON45570

Source
ToetsingOnline

Brief title
FASTING-study

Condition

- Appetite and general nutritional disorders

Synonym
Fasting duration

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Mediq TEFA

Intervention

Keyword: Dopamine, Fasting, Serotonin, SPECT-scan

Outcome measures

Primary outcome

Differences in cerebral availability of SERT and DAT (assessed by [123I]FP-CIT SPECT) after 12 vs 24 hours of fasting.

Secondary outcome

To determine the effect of the fasting duration on peripheral neuropeptides and hormones in relation to cerebral SERT and DAT availability and feeding behaviour

To determine the effect of fasting duration on resting energy expenditure (REE) in relation to cerebral SERT and DAT availability and feeding behaviour

To determine the effect of fasting duration on appetite and feeding behaviour in relation to cerebral SERT and DAT availability

To determine whether fasting affects lean and obese subjects differently

Study description

Background summary

Feeding behaviour is regulated by a complex interplay of the homeostatic and hedonic systems, and is influenced by peripheral inputs. The neurotransmitters serotonin and dopamine have major roles in the cerebral regulation of feeding behaviour by mediating anorexigenic and orexigenic signals, respectively. Cerebral availability of the serotonin and dopamine transporters (SERT and DAT) is representative of the cerebral serotonin and dopamine system.
In obesity, control of food intake is disturbed, resulting in overconsumption of high-calorie nutrients. Therefore, the role of the central nervous system, and SERT and DAT in particular, in the current obesity epidemic is an active interest of ongoing research worldwide.
Fasting influences neural signals and hormones that provide cognitive and peripheral input to the central regulation of food intake. Studying the effects

of fasting on the brain areas involved in overeating/obesity, as well as differences in the response to fasting between lean and obese individuals, may unravel novel therapeutic targets for (the prevention of) obesity.
In addition, since it is currently unknown how fasting affects central SERT and DAT, interpretation of previous studies that investigate effects of lifestyle, diet and/or metabolic challenges on cerebral serotonin and dopamine in humans is complicated. These studies vary in fasting duration prior to the measurement of cerebral SERT and DAT availability, possibly confounding the results.

Study objective

To investigate the effect of fasting duration on cerebral SERT and DAT availability.

Study design

Randomized controlled crossover study

Study burden and risks

Subjects will visit the AMC on two occasions. Prior to these visits, subjects will consume a standardized eucaloric diet for three days. After 12 or 24 hours of fasting, central SERT and DAT availability will be assessed by SPECT using an intravenous infusion of the radioligand [123I]FP-CIT. [123I]FP-CIT has a European (CPMP) registration, and it has been shown that it has no serious side effects. As the dose equivalent per [123I]FP-CIT injection amounts to 2.4 mSv (100MBq), the total dose equivalent of the subjects will be 4.8 mSv. Venous blood samples will be drawn on both visits. Risks associated by participation (thyroid uptake of radioligand, exposure to radiation) will be kept to a minimum by providing subjects with potassium iodide tablets to reduce uptake of the radioligand in the thyroid, and keeping the total dose equivalent far below the currently recommended maximum dose equivalent for research participants (i.e., 15.3 mSv (222 MBq), WHO category IIb, men >50 years).

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

Male, age 50-80 years, stable weight three months prior to study inclusion, BMI: <25kg/m2 for lean subjects and >30kg/m2 for obese subjects.

Exclusion criteria

Use of any medication except for those related to treatment of components of the metabolic syndrome.
Use of exogenous insulin or oral glucose lowering drugs
Any actual medical condition except for treated hypothyroidism and the metabolic syndromeHistory of any psychiatric disorder
Shift work
Irregular sleep pattern
Intensive sports (>3 h/week)
Restrained eaters
History of eating disorders (anorexia, binge eating, bulimia)
Smoking, XTC, amphetamine or cocaine abuse
Alcohol abuse (>3 units/day)
Lactose intolerance
Estimated glomerular filtration rate <60 ml/min
Contraindication to MRI scanning (claustrophobia, metal foreign objects)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL59923.018.16