Do high plasma free fatty acids lower central serotonergic responsivity?

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Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON33757

Source
ToetsingOnline

Brief title
SSRI

Condition

- Hypothalamus and pituitary gland disorders
- Lipid metabolism disorders

Synonym
Fat metabolism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Free fatty acids, Hypothalamus, Prolactin respons

Outcome measures

Primary outcome

Prolactin response as a reflection of serotonergic response in the

hypothalamus.

Secondary outcome

na

Study description

Background summary

SSRI's causes pituitary prolactin secretion. Atherosclerosis and metabolic syndrome causes blunted prolactin response. Both diseases are associated with elevated free fatty acids. Patient with familial combined hyperlipidemia (FCH) also have high free fatty acids. Studies in rodents suggest an important role in the regulation of triglyceride synthesis, an important aspect of the dyslipidemic components of FCH. In this study we will get more insight in the effect of serotonergic functionality with and without high free fatty acids with a citalopram provocation test.

Study objective

Do high plasma free fatty acids lower central serotonergic responsivity?

Study design

Serotonergic responsivity is measured after administration of a selective serotonin reuptake inhibitor, citalopram. This will be done in 10 healthy subjects will visit the AMC 3 times.
Visit 1 Screening, with general physical check up, and 1 blood withdrawal
Visit 2 Standardized infusion of SSRI with or without increase of free fatty acids or water.
Visit 3 Standardized infusion of SSRI with or without increase of free fatty acids or water, opposite to visit 2.

Intervention

Infusion with free fatty acids, heparin and citalopram

Study burden and risks

Healthy volunteers will visit our clinic three times. A total of 490 ml venous blood will be drawn. A selective serotonine reuptake inhibitor is giving as a standardized serotonergic test. The side effects of selective serotonin reuptake inhibitor, heparin and Intralipid are described in the protocol.

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, 18-60 years old, BMI 20-25, stable for 3 months prior the study.

Exclusion criteria

BMI between19-25, Lipid disorder, alchohol abuse, smoking, active disease influencing the protocol, irregular eating patterns, diabetes, brain disease, intense training, medication influencing the nervous system. DM or DM in first degree family member.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Citalopram
Generic name:	Citalopram
Product type:	Medicine
Brand name:	Heparin
Generic name:	Heparin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Intralipid

Generic name:	Intralipid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-08-2009
Application type:	First submission
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
EudraCT	EUCTR2009-010061-23-NL
CCMO	NL25223.018.09