# Do high plasma free fatty acids lower central serotonergic responsivity?

Published: 12-08-2009 Last updated: 06-05-2024

Do high plasma free fatty acids lower central serotonergic responsivity?

**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

1 - Do high plasma free fatty acids lower central serotonergic responsivity? 4-05-2025

#### **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 citalogram

2 - Do high plasma free fatty acids lower central serotonergic responsivity? 4-05-2025

#### 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**

#### **Public**

Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam NL

**Scientific** 

Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam NL

## **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