

Is the hypothalamic neural activity disturbed in patients with familial combined hyperlipidemia?

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1. To evaluate whether patients with FCH have different pattern of hypothalamic neural activity compared to healthy control subjects, 2. To evaluate whether patients with FCH (index patients) have a different pattern of hypothalamic neural activity...

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON31970

Source

ToetsingOnline

Brief title

FCH and Hypothalamic Neural Activity

Condition

- Coronary artery disorders
- Lipid metabolism disorders

Synonym

familial combined hyperlipidemia

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FCH, hypothalamus, metabolism

Outcome measures

Primary outcome

1. differences in hypothalamic neural activity (and suppressive effect after oral glucose load) between patients with FCH and healthy volunteers

Secondary outcome

mean change (in %) in beat-to-beat variation (lead III heart rhythm recording) during study protocol

Study description

Background summary

Familial combined hyperlipidemia (FCH) is a frequently occurring disorder with presence of dyslipidemia (elevated plasma triglyceride and cholesterol levels) and premature atherosclerotic disease. Despite intensive research the last two decades, the origin of FCH is still unresolved. Recent results from rodent models suggest a dominant role of hypothalamic activity in the regulation of triglyceride metabolism. In this background, we will evaluate whether hypothalamic neural activity is different in patients with FCH compared with healthy control subjects.

Study objective

1. To evaluate whether patients with FCH have different pattern of hypothalamic neural activity compared to healthy control subjects,
2. To evaluate whether patients with FCH (index patients) have a different pattern of hypothalamic neural activity compared to their gene-related relatives that do not display FCH and a similar pattern of hypothalamic neural activity with those who display FCH.

Study design

Randomized, single blind, case-control study. Patients with FCH (protocol A and B), and matched healthy volunteers (protocol A), and gene-related relatives

(protocol B) will be scanned three times (protocol A) and two times (protocol B) for analysis of hypothalamic neural activity by assessing change in blood oxygen level-dependent (BOLD) contrast after ingestion of a glucose solution or water using functional magnetic resonance imaging (fMRI).

Study burden and risks

Beside the investment of time and being fasting before subsequent visits (depending on which protocol), no complications or risks are expected during the procedures. The amount of glucose that will be drunk will give no-side effects and is similar or less to that used in the conventional oral glucose tolerance test.

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 patients (index patients in protocol B) with proven FCH (combined hyperlipidemia, premature atherosclerosis, positive family history for dyslipidemia and premature mortality (before age of 55 yrs))

Age 18-60 yr

Exclusion criteria

BMI > 25 kg/m² or BMI < 19 kg/m²

Current or past history of alcohol intake > 2E/day

Smoking

Presence of active disease or past disease (that may affect variables measured in this protocol)

Irregular diet habits

Slimming or having a diet on medical indication

Medication (including those with central activity, e.g. antidepressants)

Claustrophobia

Diabetes or a family history positive for diabetes

Metal implants or metal objects that cannot be removed (e.g. piercings)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	25

Type:

Anticipated

Ethics review

Approved WMO

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

CCMO

ID

NL22582.018.08