postprandial Lipidmetabolism in hMe subjects and healthy controls

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In this study, we will evaluate if these HME subjects are characterized by impaired postprandial lipid clearance compared to otherwise healthy control subjects

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON37127

Source
ToetsingOnline

Brief title
LIME study

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Lipid metabolism disorders

Synonym
postprandial dyslipidimia, postprandial lipidmetabolism disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZONMW (venibeurs dr. M. Nieuwdorp)

Intervention

Keyword: heparansulfate, hereditary multiple exostoses, type 2 diabetes mellitus lipidmetabolism

Outcome measures

Primary outcome

Changes in postprandial trygliceride levels in HME subjects vewith either EXT1

or EXT2 mutation compared to unaffected, healthy control subjects

Secondary outcome

Changes in cardiovascular risk profile (lipidprofile, ECG changes) in HME

subjects vewith either EXT1 or EXT2 mutation compared to unaffected, healthy

control subjects

Study description

Background summary

Postprandial dyslipidemia is contributing to an atherogenic state and subsequent cardiovascular disease. Novel insights in the pathophysiology are urgently needed. Recent studies in mice have suggested that endothelial and hepatic heparansulfates are involved in (postprandial) lipid clearance.
Patients with EXT-1 and EXT-2 mutations are characterized by the hereditary multiple exostoses/multiple osteochondromas (HME/MO) syndrome, an autosomal dominant syndrome causing multiple benign epiphysial bone tumors during (pre-) puberty due to 50% reduction in heparansulfate synthesis.

Study objective

In this study, we will evaluate if these HME subjects are characterized by impaired postprandial lipid clearance compared to otherwise healthy control subjects

Study design

observational study with functional (lipidload and LPL) tests

Study burden and risks

No disadvantageous effects are expected in this study. The ingestion of cream is unpleasant but unharmful. The LPL test is a test routinely performed at our outpatient clinic with no know side effects. Hypertriglyceridemia is important partaker in cardiovascular morbidity and mortality in the coming decades. Unfortunately, the exact causes for in the development of hypertriglyceridemia needs further clarification, only then allowing targeted novel strategies to attenuate this greatly increased cardiovascular risk In the present study we will compare the impact of a monogenetic heparansulfate mutation (EXTgene) in HME subjects on postprandial lipidmetabolism to healthy controls.

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 and female subjects at least 18 years of age
Clinically esthablished diagnosis of HME or unaffected, healthy control
willing to stop ATII/ACE inhibitors (5 days) and statin (4 weeks) before lipidload

Exclusion criteria

Current diabetes
Current pregnancy
Malignancy with limited lifespan -Cardiovascular disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2012
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
CCMO	NL42142.018.12