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Glucose metabolism in familial hypobetalipoproteinemia

Submission date	Recruitment status
07/06/2006	No longer recruiting
Registration date	**Overall study status**
07/06/2006	Completed
Last Edited	**Condition category**
10/11/2011	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
FHBL

Study objectives
Patients with familial hypobetalipoproteinemia (FHBL) could have increased hepatic glucose production because of hepatic steatosis. In addition, peripheral insulin sensitivity could be enhanced since these patients have lower concentrations of intramyocellular lipids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Familial hypobetalipoproteinemia (FHBL), hepatic steatosis

Interventions
A hyperinsulinaemic clamp will be performed for 4.5 hours
using stabile isotopes (d2-glucose and D5-glycerol). In addition, muscle
biopsies will be taken and fat distribution will be studied by a dual energy x-ray absorptiometry (DEXA)-scan, a
computed tomography (CT)-scan and magnetic resonance spectroscopy (MRS). Patients with FHBL will be compared to healthy
controls matched for age,sex, BMI and waist circumference.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Insulin sensitivity at the level of glucose production by liver, glucose uptake by muscle and fat and lipolysis
2. Fat distribution by a DEXA, a CT-scan and MRS-spectroscopy

Secondary outcome measures
1. Lipid levels
2. Glucoregulatory levels
3. (Adipo)cytokines

Overall study start date
11/05/2006

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. Male
2. Age >18 years of age
3. Body mass index (BMI) 20-35 kg/m^2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
22

Key exclusion criteria
1. Known somatic illness
2. Use of medication influencing metabolism or blood clotting
3. Seropositive for hepatitis B surface antigen (HbsAg), hepatitis B surface antigen (HbcAg), hepatitis C virus (HCV), hepatitis A virus (HAV) or human immunodeficiency virus (HIV)
4. Having a metal device in the body

Date of first enrolment

11/05/2006

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
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Sponsor information

Organisation
Academic Medical Center (AMC), Department of Endocrinology and Metabolism (The Netherlands)

Sponsor details
P.O. Box 22660
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Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Center (AMC), Department of Endocrinology and Metabolism

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2011		Yes	No