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Glucose metabolism in familial hypobetalipoproteinemia

Submission date	Recruitment status	[_] Prospectively registered
07/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2011	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr R. Blumer

Contact details
Academic Medical Center (AMC)
Department of Endocrinology and Metabolism
F5-162
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5669111
r.blumer@amc.uva.nl

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
1. Lipid levels
2. Glucoregulatory levels
3. (Adipo)cytokines

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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
Netherlands
1100 DD

Sponsor information

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

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

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