Glucose metabolism in familial hypobetalipoproteinemia

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

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

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

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

Secondary outcome measures

Lipid levels
 Glucoregulatory levels

3. (Adipo)cytokines

Overall study start date

11/05/2006

Completion date

01/10/2006

Eligibility

Key inclusion criteria

Male
 Age >18 years of age
 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 Netherlands 1100 DD

Sponsor information

Organisation

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

Sponsor details

P.O. Box 22660 Amsterdam Netherlands 1100 DD

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?
<u>Results article</u>	results	01/08/2011		Yes	No