Effects of a low-fat vs a high-fat diet on lipid accumulation in liver, skeletal muscle and heart in overweight man

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The major research objective is:Does a switch from a low-fat to a high-fat diet lead to a reduced hepatic and skeletal muscle insulin sensitivity due to an increase lipid accumulation in liver, skeletal muscle and heart? Secondary research...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON33743

Source
ToetsingOnline

Brief title
Diet and lipid accumulation

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: TIFN (formerly known as WCFS),Top

Institure for Food and Nutrition (TIFN) (formerly known as WCFS). Het TIFN is de subsidierende partij;maar NUTRIM is de verrichter.

Intervention

Keyword: High-fat diet, lipid accumulation, liver, MRS

Outcome measures

Primary outcome

Main study parameter is the difference in insulin sensitivity after a switch

from a low-fat diet to a high-fat diet compared to the control group, which

stays on a low-fat diet.

Secondary outcome

As secondary endpoints differences in lipid accumulation in heart liver and

muscle, cardiac function, the time-course of lipid accumulation and the

relationship between the tissue parameter lipid accumulation and the functional

outcome parameter insulin resistance are considered.

Study description

Background summary

Intramyocellular lipid (IMCL), Intrahepatic lipid (IHL) and Intracardiac lipids (ICL) are important features of the metabolic syndrome and its complications. Although, it is known that diet can influence IMCL and IHL in rodents and in humans, the time-course of peripheral lipid accumulation and its relationship with tissue specific insulin while switching from a low-fat to a high-fat diet is unknown. Also the relationship between cardiac lipid accumulation and cardiac function is unknown.

Study objective

The major research objective is:
Does a switch from a low-fat to a high-fat diet lead to a reduced hepatic and skeletal muscle insulin sensitivity due to an increase lipid accumulation in

liver, skeletal muscle and heart?
Secondary research objectives are:
o Does a switch from a low-fat to high-fat diet lead to lipid accumulation in liver, heart and muscle
o To establish the time-course of lipid accumulation in liver following a short-term dietary intervention
o To establish the relationship between the tissue parameter lipid accumulation and the functional outcome parameter insulin resistance
o To establish the relationship between cardiac lipid accumulation and cardiac function.

Study design

In this project we will examine the effect of an increase in dietary fat intake on intrahepatic, intramyocellular and intracardiac lipid accumulation in relation to insulin sensitivity and cardiac function. Basal measurements will be made after a 3-week low-fat diet (run-in), after which half of the subjects will switch to a 3 week high-fat diet (experimental group), and half of the subjects will remain on the low-fat diet (control group).
The low-fat diet which will deliver 15 Energy% of energy as protein, 65 En% as CHO and 20 En% as fat. The high-fat diet will consist of 15 En% protein, 30 En% CHO and 55% En% fat).

Study burden and risks

Before the start of the study subjects will be screened to access eligibility (visit duration: 30 min). After screening also body composition and maximal endurance capacity will be measured (60 min)
Subsequent each subject will be randomly allocated to the control or the experimental group. The subjects will visit the department 4 (control group: day 0-21-28-42) or 6 times (experimental group: day 0-20-21-28-41-42) during the 6-weeks study period. During these visits two blood samples, two hyperinsulinemic-euglycemic clamps, including 2 muscle biopsies during each clamp, will be performed; 5 MRS-sessions will take place in the experimental group and 2 MRS-sessions in the control.
Venapuncters and muscle biopsies can cause local hematomas; the muscle biopsy can result in some discomfort the day after.

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 sex
• Age 18-65 years
• BMI 25-35 kg/m2
• Sedentary
• Stable dietary habits
• Healthy
• Not wanting to be informed about a conincedence finding.

Exclusion criteria

• Current use of medication that is known to interfere with the results of the study.
• Consuming more than 20 g of alcohol per day (± 2 units)
• Serum-γ-glutamyltranspeptidase level > 70 IU/L
• A history of cardiovascular disease like congestive heart failure or acute myocardial infarction
• Plasma triacylglycerol > 4.5 mmol/L
• Familial hypercholesterolemia
• A history of liver disease

• Unstable body weight (weight gain or loss > 3 kg in the past three months)
• Abuse of drugs
• Participation in another biomedical study within 1 month prior to the screening visit
• Impossible or difficult venipuncture during screening
• a fasting glucose above 7.0 mmol/L
• a contraindication to MRI scanning. These contraindications include patients with the following devices:
o Central nervous system aneurysm clips;
o Implanted neural stimulator;
o Implanted cardiac pacemaker or defibrillator;
o Cochlear implant;
o Ocular foreign body (e.g. metal shavings);
o Insulin pump;
o Metal shrapnel or bullet;
o Or metal containing corpora aliena in the eye of brains

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2007
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	14-05-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-01-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL16162.068.07