Effects of fatty acids on postprandial inflammatory response van healthy obese and type 2 diabetic obese subjects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33112

Source
ToetsingOnline

Brief title
PIFA study (Study on Postprandial Inflammation and Fatty Acids)

Condition

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

Synonym
the molecular and biochemical mechanism of fatty acids in blood cells

Health condition

obese en gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Diabetesfonds

Intervention

Keyword: fatty acids, inflammation, nutrigenomics, peripheral blood mononuclear cells

Outcome measures

Primary outcome

PBMC gene expression profiles

Secondary outcome

PBMC inflammatory response capacity

Endothelial function

Tertiar:

lipid profiles

plasma glucose and insulin

monocyte and lymfocyte gene expression profiles

Study description

Background summary

Consumption of high-fat diets can lead to postprandial dyslipidemia, impairment of endothelial function, activation of immune cells and changes in gene expression profiles of immune cells such as peripheral blood mononuclear cells (PBMC).
Recently it was shown that postprandial gene expression profiles of PBMC and plasma triglyceride (TG) and free fatty acid (FFA) responses are dependent on the type of dietary fat consumed (i.e. saturated, monounsaturated and polyunsaturated). Since obese and diabetic subjects usually are in a pro-inflammatory state and have dyslipidemia and endothelial dysfunction we are

interested in the effect of different fatty acids in a high load on the PBMC gene expression profiles, plasma cytokine profiles and endothelial function of these subjects.

Study objective

The main objective is to elucidate the acute effects of an oral intake of either saturated, monounsaturated or polyunsaturated fatty acids on PBMC whole genome expression of obese and type 2 diabetic obese subjects.
Secondary objectives are to elucidate the acute effects of the fat loads on PBMC inflammatory response capacity and endothelial function of these subjects.
Tertiary objectives are to investigate the effects of the fat loads in the groups of subjects on plasma lipid profiles, plasma glucose and insulin and on monocyte and lymphocyte whole genome expression.

Study design

Single blind cross-over intervention

Intervention

Elke participant will consume 3 high-fat milkshakes differering in fatty acid composition (saturated fat, monounsaturated fat and polyunsaturated fat)

Study burden and risks

During a screening visit 3 ml blood will be drawn and urine will be collected after a overnight fast and body weight, length, waist and blood pressure will be measured. An oral glucose tolerance test will be performed. A general and medical questionnaire will be used.
During the study period of 8 weeks each participant will visit the university on 3 mornings, separated by at least one week, and will consume within 15 minutes a milkshake containing 95 grams of fat. Blood will be collected and endothelial function will be measured both before consuming the milkshakes (baseline, T=0) and 2 hrs (T=2) and 4 hrs (T=4) after consumption of the shakes. Blood will be drawn by normal venopuncture. At time points 0 and 2 hrs 60 ml blood will be collected and at time point 4 hr 52 ml will be collected, bringing it to a total of 172 ml per day. Hb values of each participant will be monitored during the study to be sure that blood collection will not lead to anaemia.
Participants have to collect a small amount of faeces at one time point during the study period. The body composition of the participants will be measured in the Bod Pod. In addition, the participants will visit the radiology department of the hospital Gelderse Vallei in Ede for a MRI scan to determine their abdominal bodyfat distribution.
The time investment requested from the participants is 1 hour at the

information meeting, 2.5 hours at a screening session, 3 x 4.5 hours at the intervention days and 1 hour for the MRI scan. The risks associated with venous blood drawing by venopuncture are minimal. The consumption of the milkshakes is not expected to be associated with discomfort, but could, in rare cases, have adverse effects such as a mild gastrointestinal discomfort (fishy aftertaste in case of PUFA shake, belching, flatulence or loose stools). MRI is a safe procedure, with no known health risk as long as no contraindication is met (see paragraph 9.4.3). MRI can result in a *coincidence* finding. These findings should be reported and subjects will be informed about this.

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

Inclusion criteria for all participants:

- male gender
-50-70 yrs
For diabetic patients only:
- BMI >30 kg/m2
- Well-controlled diabetes: fasting plasma glucose concentration must be <10.0 mmol/l at the time of screening.
- Must be on sulphonylurea- or metformin therapy for at least 6 months with a constant dose for at least two months, or on dietary treatment for at least 6 months2.
For obese controls only:
- BMI > 30 kg/m2
- normoglycemic according to WHO criteria (OGTT, fasting blood glucose< 7 mmol/L, after 2 hr <7.8mmol/L)
For lean controls only:
- BMI 18-25 kg/m2
- normoglycemic according to WHO criteria (OGTT, fasting blood glucose< 7 mmol/L, after 2 hr <7.8mmol/L)

Exclusion criteria

Exclusion criteria for all participants:
All subjects:
- Female gender
- Age below 50 or above 70 years
- Hemoglobin levels <8.4 mmol/L
- Allergic to cow milk or dairy products
- Allergic to fish oil
- Vegetarian
- Tobacco smoker
- Current or recent (<4 weeks) use of fish oil supplements or more then four times fish/week; 24.35 g of EPA-DHA of fish per month (800 mg/day) as judged by the questionnaire.
- Received inoculations within 2 months of starting the study or planned to during the study
- Donated or intended to donate blood from 2 months before the study till two months after the study
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Medical condition that can interfere with the study outcome (i.e. cardiovascular disease, gastrointestinal disease, renal dysfunction)
- Use of medications know to interfere with glucose homeostasis (i.e. corticosteroids)
- abuse of drugs and/or alcohol
- participation in another biomedical study within 1 month before the first screening visit;For obese, type 2 diabetic subjects only:
- severe diabetes which requires application of insulin
- diabetes-related complications
For obese subjects and lean controls only:
- hyperglycemic according to WHO criteria (OGTT, fasting blood glucose >6.0mM, after 2 hr>11mM)

-systolic blood pressure >160 mmHg or diastolic blood pressure > 100 mmHg
- Urinary glucose concentrations (>0.25 g/l)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2009
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2009
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	19-10-2009
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	06-11-2009
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL28001.081.09