The effects of dietary fatty acids on postprandial markers for inflammation in healthy overweight men

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The objective is to study whether saturated fatty acids induce a different postprandial change in inflammatory markers than cis-polyunsaturated fatty acids.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON32478

Source
ToetsingOnline

Brief title
Fatty acids and postprandial inflammation

Condition

- Coronary artery disorders
- Metabolism disorders NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerosis, hardening of the arteries, insulin resistance syndrome ;atherosclerosis, metabolic syndrome, syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Nederlandse Zuivel Organisatie (NZO)

Intervention

Keyword: cardiovascular disease, inflammation, metabolic syndrome, saturated fatty acid, unsaturated fatty acid

Outcome measures

Primary outcome

The primary study endpoints are levels of interleukin-6 and levels of other

markers of postprandial inflammation, including TNF-alpha, MCP-1, interleukin-1

and interleukin-8.

Secondary outcome

Secondary study parameters include markers of insulin resistance, plasma lipids

and lipoproteins.

Study description

Background summary

The prevalence of Metabolic Syndrome (MS) is rapidly increasing. MS is a condition characterized by central obesity, a proinflammatory state and disturbed levels of cholesterol and plasma lipids. Being overweight is a major risk factor for developing MS. People with MS are at increased risk for type 2 diabetes and cardiovascular disease, an inflammatory disease, which is still the leading cause of death in western countries.

Several studies have shown that dietary fatty acids induce differential postprandial responses. It is suggested that the postprandial response to dietary fatty acids differs according to type of fat, chain length, degree of saturation and triacylglycerol solid fat content. Because information is still lacking, this study investigates the differences in postprandial inflammation between saturated fatty acids and cis-polyunsaturated fatty acids.

Study objective

The objective is to study whether saturated fatty acids induce a different

postprandial change in inflammatory markers than cis-polyunsaturated fatty acids.

Study design

Randomized, double-blind, cross-over design. During two test days, subjects receive in a randomized order a meal rich in butter (62g) or rich in margarine + safflower oil (40 + 10g). During the subsequent 8 hours blood samples are drawn for determining plasma markers of inflammation and plasma lipids and lipoproteins. Subjects are invited for the second visit with a period of at least 7 days in between, where they receive the remaining meal according to the same procedures as the first meal.

Intervention

The test meals are provided as cupcakes. In the butter meal 61,65g butter is added to 60g flower, 60g sugar and 60g of whole egg. In the margarine meal 50g margarine in combination with 10g safflower oil is added to 60g flower, 60g sugar and 60g of whole egg. In addition, 11,8g of egg yolk is added to the margarine meal in order to standardize cholesterol content between both meals. The cupcakes are designed to provide 50g of test fat.

Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during two 20 min visits. During these visits, body weight, height and blood pressure is measured, and a blood sample (4 mL) is drawn by means of venapunction. Subjects are also asked to fill in two questionnaires. Consequently, each subject will be allocated to one of two meals (butterfat meal or margarine meal) in a random order. In the test period, the subjects will visit the department 2 times. During these visits, an intravenous cannula will be inserted in an antecubital vein and when the subjects consume the test meals 12 blood samples are drawn during 8 hours. Total blood sampling volume during the study is 258 mL and total time investment for the subjects will be approximately 17 hours. During this period, subjects will be at the university. During the period between test days, subjects keep a record of any symptoms of disease or discomfort and possible irregularities. Even though blood sampling is performed by a competent person bruises or haematoma may occur.

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

men
BMI in the range of 25-30 kg/m2
age between 18 and 70
no treatment with lipid-lowering (Dutch Cholesterol Concensus)

Exclusion criteria

- Women
- Plasma triacylglycerol >= 1.7 mmol/L (150 mg/dL)
- Smoking
- Lipid-lowering medication/therapy
- Familial hypercholesterolemia
- Use of drugs
- Alcohol consumptions >14/week
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Severe medical conditions, which might interfere with the study, such as epilepsy, asthma, COPD,

inflammatory bowel diseases and rheumatoid arthritis.
- Active CVD or recent event in the past 6 months (acute myocardial infarction, stroke)
- Participation in another intervention study within 1 month preceding the screening visit
- Blood donation within 1 month prior to the screening visit or planning to do so during the study
- Impossible or difficult venapunction during screening

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	03-11-2008
Application type:	First submission
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	NL24301.068.08