

The effects of triacylglycerol structure of palmitic acid rich fats on postprandial changes in lipid and glucose metabolism

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To compare effects of native palm olein with those of interesterified palm olein on postprandial lipid and glucose metabolism

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON33469

Source

ToetsingOnline

Brief title

Dietary fats and postprandial metabolism

Condition

- Lipid metabolism disorders

Synonym

disturbances during the postprandial state, metabolic disturbances after a meal

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Beleidsreserve afkomstig van industriële projecten

Intervention

Keyword: Dietary fats, Palmitic acid, Postprandial metabolism, Triacylglycerol structure

Outcome measures

Primary outcome

Metabolic risk markers related to cardiovascular disease: Primary endpoints are postprandial lipemia and glycemia.

Secondary outcome

Secondary endpoints are changes in postprandial concentrations of insulin, and factors related to low-grade systemic inflammation and clotting activity, and of gut hormones.

Study description

Background summary

Interesterification of fats and oils, a process used to change their functional characteristics, is a widely used process. It results in a re-arrangement of the fatty acids of the triacylglycerol molecule, thereby affecting triacylglycerol structure. The majority of studies have not demonstrated unwanted effects of such interesterified fats on the fasting serum lipoprotein profile. Effects on postprandial metabolism however have less extensively been studied.

Study objective

To compare effects of native palm olein with those of interesterified palm olein on postprandial lipid and glucose metabolism

Study design

Using a randomized crossover design study, subjects will receive in random order 4 experimental meals with a washout period of at least 7 days. During each test, the postprandial response is measured. The study is part of an international multi-centre study in collaboration with the Nutritional Sciences Division, King's College London, UK (Professor T.A.B. Sanders and Dr S.E.

Berry).

Intervention

All subjects will receive four meals in a random order, a meal rich in palm olein, interesterified palm olein, lard, or high-oleic acid sunflower oil (control).

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. In addition, a blood sample (2x4 mL) is drawn by means of venapunction. Each subject will receive products enriched with four different fats in random order. For this, subjects have to visit the department 4 times. During these visits, an intravenous cannula is inserted in an antecubital vein. Just before and after meal consumption, 13 blood samples (4x130 mL) are drawn during 8 hours. Total time investment for the subjects will be approximately 33 hours. During this period, subjects will be at the university. On rare occasions, blood sampling might cause bruises or hematoma.

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

Body mass index (BMI) between 20-35 kg/m²

Age: 18-45 years

Serum total cholesterol < 7.8 mmol/L

Serum triacylglycerol < 3.0 mmol/L

Plasma glucose: < 7 mmol/L

Exclusion criteria

- Smoking
- (Drug treatment against) Diabetes Mellitus
- Cardiovascular disease
- Familial hypercholesterolemia or lipid-lowering medication
- Diseases that can interfere with the outcome of the studies such as: COPD, asthma, epilepsy, IBD, rheumatoid arthritis
- Unstable body weight (>3 kg weight gain or weight loss during the past 3 months)
- Abuse of drugs or alcohol (>28 consumptions a week)
- Participation in another trial or use of experimental products during the last months
- Having donated blood during the last two months
- Difficult or impossible to puncture during screening
- Not willing to consume animal-derived products

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 08-04-2009
Enrollment: 28
Type: Actual

Ethics review

Approved WMO
Date: 30-03-2009
Application type: First submission
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO
Date: 29-04-2009
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

CCMO

ID

NL26787.068.09