Effects of C16:0 versus C18:0 on HDL metabolism and other cardiometabolic risk markers:
A dietary intervention study in healthy normal-weight and overweight subjects

Published: 16-03-2016
Last updated: 19-04-2024

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

Summary

ID

NL-OMON46224

Source
ToetsingOnline

Brief title
PASTEL
(PAlmitic acid STEaric acid and Lipoproteins)

Condition

- Other condition

Synonym
HDL-metabolism, risk factors for cardiovascular disease

Health condition

Metabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Unilever

Intervention

Keyword: HDL-metabolism, Human intervention study, Palmitic acid, Stearic acid

Outcome measures

Primary outcome

The primary study parameter is the change in HDL metabolism during the fasted state at the end of the dietary period high in palmitic acid versus the dietary period high in stearic acid.

Secondary outcome

Secondary study parameters are the effects of palmitic acid versus stearic acid on fasting LDL-C, HDL-C, total cholesterol, the total cholesterol to HDL-C ratio, the LDL-C to HDL-C ratio, non-HDL cholesterol, apoAI and apoB100, and on fasted and postprandial triacylglycerol concentrations.

Study description

Background summary

Dietary recommendations to prevent coronary heart disease (CHD) are focused on lowering cholesterol concentrations in the atherogenic low-density lipoproteins (LDL-C) by decreasing the intake of saturated fatty acids (SAFAs). However, SAFAs refer to a mixture of different fatty acids, predominantly palmitic acid (C16:0) and stearic acid (C18:0). Stearic acid lowers LDL-C as compared with palmitic acid. However, whether palmitic and stearic acids truly have different cardiometabolic effects is unknown, as LDL-C is not the only determinant of cardiovascular health. For example, stearic acid lowers cholesterol

concentrations in the *anti-atherogenic* high-density lipoprotein particles (HDL-C) compared with palmitic acid. Simply increasing HDL-C levels, however, does not necessarily lower CHD-risk. In this respect, targeting HDL-functionality is more important. Effects of palmitic acid and stearic acid on HDL-functionality have never been compared.

Study objective

The primary objective of the present study is to investigate the effect of palmitic acid versus stearic acid on HDL metabolism during the fasted state. Secondary objectives are to investigate the effects of palmitic acid versus stearic acid on the fasting serum lipoprotein profile, and on fasted and postprandial triacylglycerol concentrations. Exploratory objectives are to investigate the effect of palmitic acid versus stearic acid on other markers of fasting lipid metabolism, glucose metabolism, inflammation, endothelial function and blood pressure.

Study design

This is a double-blind, randomized, cross-over study with two different diets: one diet will be high in palmitic acid and the other diet will be high in stearic acid.

Intervention

Subjects will receive both diets for 4 weeks with a wash-out period of 4 weeks in between. Contrast in the intakes of palmitic acid and stearic acid is 6% of energy. A postprandial test will be carried out at the end of each dietary period.

Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during one 20 min visit. During this visit, body weight, and height will be measured and a blood sample (4 mL) will be drawn by means of venapunction. Thereafter, subjects will be asked to fill in a medical and general questionnaire, including information on physical activity. During the study, subjects will receive products based on the experimental fats. In addition, dietary guidelines will be provided to standardize total fat and fatty acid intake between subjects and periods. On 8 occasions a fasting blood sample will be drawn (with a total of 188 mL spread over the eight visits), body weight and blood pressure will be measured. At the last visit of each period, subjects will participate in a postprandial test. An intravenous cannula will be inserted in an antecubital vein. Before and after meal consumption, 13 blood samples (120 mL) will be drawn during an 8 hour period. During the test, subjects are allowed to drink water and to walk freely around.

Subjects may visit the research facilities in between to pick up the experimental products. All subjects will be asked to complete a food frequency questionnaire two times. Subjects will register daily the intake of the experimental foods, and the remaining products in a diary, as well as any signs of illness, medication used, and any deviations from the protocol. On rare occasions, blood sampling might cause bruises or hematoma. Total time investment for the subjects will be approximately 29 hours.

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

- Apparently healthy men and post-menopausal women (post-menopausal for at least one year)
- BMI * 18.0 and * 30.0 kg/m2

- Age: 45-70 yrs
- Signed informed consent

Exclusion criteria

- Having a medical condition which might impact study measurements
- Use of over-the-counter and prescribed medication, which may interfere with study measurements
- Use of oral antibiotics in 40 days or less prior to the start of the study;
- Use of food supplements or plant-sterol/stanol-enriched foods or supplements in the three months prior to the screening and/or during the study;
- Reported alcohol consumption * 10 units/week (female) or * 14 units/week (male);
- Reported intense sporting activities * 10 hours/week;
- Reported weight loss or gain of 3 kg or more during a period of 2 months prior to screening
- Regular smokers (at least one cigarette (or equivalent) daily or >7 cigarettes (or equivalent) weekly. Smokers who cannot comfortably restrain from smoking for up to 2 days will also be excluded
- Reported dietary habits: medically prescribed diet, allergy/intolerance to test products that will be provided during the study
- Blood donation in the past 3 months
- Drug abuse
- Reported participation in another nutritional or biomedical trial 3 months prior to screening
- Fasting triacylglycerol concentrations at screening: * 4.5 mmol/L
- Serum lipids: treatment recommended according to the *Multidisciplinaire richtlijn Cardiovasculair risicomanagement*
- Fasting HbA1c * 48 mmol/mol (or 6.5%)

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2016

Enrollment:	43
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2017
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
Other	Na METC goedkeuring wordt het in ClinicalTrials.gov geregistreerd
CCMO	NL55130.068.15