Interesterified fats: Health effects of commercially relevant palmitic versus stearic acid rich interesterified fats

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To compare the effects of commercially relevant IE palmitic and stearic acid rich fat blends on fasting and postprandial cardiometabolic risk parameters after chronic exposure to these fats.

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

Summary

ID

NL-OMON48329

Source
ToetsingOnline

Brief title
InterSat
(Interesterified saturated fatty acids)

Condition

- Other condition

Synonym
lipoprotein 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: Malaysian Palm Oil Board

Intervention

Keyword: Cardiovascular risk, Human intervention study, Interesterified fat, Saturated fatty acids

Outcome measures

Primary outcome

The main study endpoint is the difference in the total to HDL-cholesterol ratio

as measured at the end of the intervention periods.

Secondary outcome

Secondary endpoints include the postprandial lipidemic and glycaemic effects

after chronic exposure to these fats.

Study description

Background summary

Random interesterification is extensively used by the food industry to create fats with desirable functional characteristics for use in spreads and bakery products without the use of trans fatty acids (FA) or animal fats and with a lower saturated FA (SFA) content. Randomly interesterified (IE) fats rich in palmitic and stearic acids are the most commonly used IE fats by the food industry. Palmitic-acid rich IE fats are generally used by the European market and derived from palm fruits and include palm oil fractions such as palm stearines (PSt) (high in palmitic acid) and, in smaller proportions, palm kernel oil (PK) or coconut oil (both rich in lauric acid). Stearic-acid rich IE fats are generally used by the North American market and typically are derived from fully hydrogenated soybean (FHS) IE with vegetable oils. Despite their widespread use, there has been no published research on the cardio-metabolic health effects of the most commonly consumed palmitic and stearic acid rich IE fats.

Study objective

To compare the effects of commercially relevant IE palmitic and stearic acid rich fat blends on fasting and postprandial cardiometabolic risk parameters after chronic exposure to these fats.

Study design

This is a double-blind, randomized, cross-over study with commercially relevant palmitic and stearic acid rich IE fats. Subjects will receive both fats for 6 weeks with a wash-out period of at least 4 weeks in between. Contrast in the intakes of the IE fats is 15% of energy. A postprandial test will be carried out at the start and the end of each dietary period.

Intervention

Following a 2-week run-in period, volunteers will be randomly allocated to test diets providing 15% energy of the hardstock from test fats (palm stearin kernel blended with rapeseed oil (PSKb) or a fully hydrogenated rapeseed oil blended with sunflower oil and coconut oil (FHRpS)) for 6 weeks with a washout period of at least 4 weeks. A subgroup will undergo postprandial test meal challenges at the start and end of each 6-week intervention on the corresponding test fat.

Study burden and risks

Before the start of the study, subjects will be screened to determine eligibility during one 15 min visit. During this visit, body weight, and height will be measured and a blood sample (7.5 mL) will be drawn by means of venapunction. Blood pressure will also be measured. 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. On 4 occasions a fasting blood sample will be drawn (with a total of 76 mL spread over the four visits), body weight, fat distribution (waist to hip ratio), and blood pressure will be measured. At the start and end of each intervention period, a subgroup will participate in a postprandial test. An intravenous cannula will be inserted in an antecubital vein. Before and after meal consumption, 14 blood samples (4x130.5 mL) will be drawn during an 8-hour period. During the test, subjects are allowed to drink water and to walk freely around. In this subgroup, liver fat will be assessed as well at the end of each experimental using magnetic resonance imaging (MRI). 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 four 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 16 hours for those who do not participate in the postprandial tests plus MRI measurements and 55 hours for

those who will participate in the postprandial test.

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 women
- Non-smoking
- Age: 35-65 yrs
- Having a general practitioner
- Signed informed consent
- Agreeing to be informed about medically relevant personal test-results by a physician
- For the subgroup (Maastricht only): No contra-indication for MRI measurements

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 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 * 21 units/week;
- Reported weight loss or gain of 3 kg or more during a period of 2 months prior to screening
- 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
- Serum lipids: treatment recommended according to the *Multidisciplinaire richtlijn Cardiovasculair risicomanagement*
- Body mass index < 20 kg/m2 or > 35 kg/m2

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2020
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2019
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
Other	Na METC goedkeuring wordt het in ClinicalTrials.gov geregistreerd
CCMO	NL70252.068.19