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The chronic effects of triacylglycerol structure of palm oil on glucose homeostasis, insulin secretion and sensitivity and lipid metabolism

Submission date
30/08/2011

Recruitment status
No longer recruiting

Registration date
19/09/2011

Overall study status
Completed

Last Edited
04/08/2014

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is well known that consuming saturated animal fats has a negative effect on blood lipid (fat) levels (for example, on cholesterol levels). Since plant fats have not been found to have the same negative effects on blood lipids and insulin activity, we think this may be due to differences in the molecular structure of the fat. In industry, plant fats are used for the manufacture of commercial bakery goods (cakes, biscuits etc.). However, plant fats need to be hardened before being used for these purposes. One way of hardening plant fats is a process known as partial hydrogenation. However, this process produces trans fatty acids, which have recently been banned in several countries after they were found to be detrimental for heart health. An alternative process now being used is known as chemical interesterification. This process takes plant fats (like palm oil) and hardens them by changing their structure so that they have a structure similar to that of hard animal fats. However, we do not know whether this change in the plant fat structure will cause the now hardened plant fat to have the same negative effects on our heart health as do animal fats. It is also unclear whether saturated plant fats behave similarly to unsaturated plant fats (such as sunflower oil). The aims of this study are to compare the long-term effects of saturated plant fats (palm oil) with an interesterified (hardened) version of the plant fat; and to determine whether palm oil (saturated plant fat) behaves any differently to sunflower oil (unsaturated plant fat). We will be looking at the long-term changes in blood lipids, glucose balance and insulin release, following diets rich in all three of the above described fats.

Who can participate?
Healthy volunteers between the ages of 20-60.

What does the study involve?
Volunteers will need to complete a screening questionnaire with us over the telephone, via email or in person (15 minutes), after which potentially eligible volunteers will be invited to attend (fasted) a clinic screening appointment (45 minutes). Height, weight, waist circumference, percentage body fat and blood pressure will be measured, and a fasting blood sample (about three teaspoons) will be taken to check for normal liver function, blood glucose,

insulin and lipids. Volunteers will also be asked to record everything they eat and drink for 3 days using an electronic food scale that will be provided to you. Participants will then be required to collect their daily breakfast, lunch and supper, freshly prepared from the canteen. Either sunflower oil, palm oil or interesterified palm oil will be used to prepare these meals. During the first 2 weeks, the same fat will be used to prepare all the meals for all the participants. Thereafter, participants will be randomly allocated to one of three groups. Every 6 weeks, the fat used to prepare your meals will change so that at the end of the 20 weeks you have spent 6 weeks on each diet. You will also be asked to attend the Metabolic Unit on eight other occasions. The first two visits will be within 5 days of each other and the remaining visits will each be separated by about 3 weeks. The 1st, 3rd, 5th and 7th visits will take about 45 minutes, where you will be asked to avoid eating or drinking anything (except water) from 10 pm the evening before, so that a fasting blood sample (about four teaspoons) can be taken. The 2nd, 4th, 6th and 8th visits will take around 2 ½ hours each. For these visits we will ask you to avoid eating fatty foods, drinking alcohol, doing any strenuous exercise, and consuming caffeine from midday the day before each study day, and to avoid eating or drinking anything (except water) from 10 pm. For these four visits you will also be provided with a standard light meal (mee soup) to consume for dinner the evening before. On the longer study days (2nd, 4th, 6th and 8th visits) a fixed needle will be inserted into your forearm on arrival at the unit and a small blood sample (about five teaspoons) will be taken. We will then ask you to eat a test meal, in the form of a muffin and a 200 ml milkshake, and further blood samples will be taken at 10-minute intervals for the first half hour and 30 minute intervals up to 2 hours after the test meal. Following the 2-hour blood sample, the fixed needle will be removed and you will be provided with a snack before you leave. Blood pressure will be measured at all eight visits, and weight once every 2 weeks.

What are the possible benefits and risks of participating?
Possible benefits will include the fact that all participants will receive a full biochemical screening (full blood count, full lipid count, liver function test and glucose levels analysis) and they will be provided with the results upon completion of the study. The risk associated with the work is minimal but blood collection does include a very small risk of bruising. There is no risk associated with the consumption of the foods to be served.

Where is the study run from?
Metabolic Unit, 5th Floor, Bangunan Pusat Inovasi, Malaysian Palm Oil Board (Malaysia).

When is the study starting and how long is it expected to run for?
The study started in February 2011 and ran for 20 weeks.

Who is funding the study?
Malaysian Palm Oil Board (Malaysia).

Who is the main contact?
Professor Tom Sanders (tom.sanders@kcl.ac.uk)
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Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7221 (NMRR research ID)

Study information

Scientific Title
The chronic effects of triacylglycerol structure of palm oil in healthy adults on glucose homeostasis, insulin secretion and sensitivity and lipid metabolism: a single-blind, randomized crossover trial

Study objectives
1. Changing the triacylglycerol (TAG) structure of palm olein by interesterification, to produce a fat with a higher proportion of palmitic acid in the sn-2 position, will alter glucose homeostasis, beta-cell activity (insulin secretion), insulin sensitivity and fasting plasma lipids.
2. Palm olein will not differ from high monounsaturated fatty acids (MUFA) oils with regards to its effects on insulin sensitivity and release.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Institute of Health (NIH), 06/01/2011

Study design
Single-centre single-blind randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
The dietary intervention will involve provision of 20% energy intake (approximately 45 g/d if based on a 2000 kcal basic diet) from the three test fats - palm olein (control), interesterified palm olein and high oleic sunflower oil (reference oil). Participants will first follow the intervention using the control test fat for 2 weeks, after which they will randomly be allocated to one of the three test diets for 6 weeks per intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. β-cell function (measured as the increments in C-peptide response to a mixed meal) will be measured at fasting, 10, 20, 30, 60, 90 and 120 minutes postprandially. These measurements will be taken at the baseline visit, 6, 12 and 18 week visits.
2. C-peptide will also be measured at fasting at the 3, 9 and 15 week visits. C-peptide will be measured using a solid-phase, two-site chemiluminescence immunoassay

Secondary outcome measures
1. Insulin and glucose concentrations will be measured at fasting (in duplicate separated by a 5-minute interval), 10, 20, 30, 60, 90 and 120 minutes postprandially at the baseline visit, 6, 12 and 18 week visits.
2. Insulin and glucose concentrations will also be measured at fasting (in duplicate as described above) at the 3, 9 and 15 week visits. Insulin will be measured using a solid phase, two-site chemiluminescence immunoassay and glucose will be measured using an endpoint enzymatic reaction.

Overall study start date
01/02/2011

Completion date
28/07/2011

Eligibility

Key inclusion criteria
Healthy male and female participants, aged between 20 and 50 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
54

Key exclusion criteria
1. Medical history of myocardial infarction, angina, thrombosis, stroke, cancer or diabetes
2. Participants with metabolic syndrome as defined by the International Diabetes Federation (http://www.idf.org/webdata/docs/MetS_def_update2006.pdf)
3. Underweight [Body mass index (BMI) < 18.5 kg/m2] or obese (BMI ≥ 30 kg/m2)
4. Plasma cholesterol > 7.0 mmol /L
5. Plasma triacylglycerol > 3 mmol /L
6. Plasma glucose > 7 mmol /L
7. Current use of antihypertensive, lipid lowering, insulin/glucose-modulating medication
8. Alcohol intake exceeding a moderate intake (> 21 units/week for males and > 14 units/week for females)

Date of first enrolment
01/02/2011

Date of final enrolment
28/07/2011

Locations

Countries of recruitment
England

Malaysia

United Kingdom

Study participating centre

150 Stamford Street
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Malaysian Palm Oil Board (MPOB) (Malaysia)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2014		Yes	No