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Effects of dietary fat structure on short term changes in blood lipids and insulin sensitivity

Submission date 26/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2009	**Overall study status** Completed	
Last Edited 07/02/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The acute effects of triacylglycerol structure of palmitic acid rich fats on postprandial changes in lipid and glucose metabolism: a randomised cross-over trial

Acronym
IPART

Study objectives
Changing the triacylglycerol structure of palm oil by interesterification, to produce a fat with a high proportion of palmitic acid in the sn-2 position, will alter postprandial lipid and glucose metabolism. Postprandial responses to plant (interesterified palm oil) and animal (lard) fats with a high proportion of palmitic acid in the sn-2 position will be similar.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Kent Research Ethics Committee gave approval on the 14th January 2009 (ref: 08/H1101 /122)

Study design
Randomised cross-over design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Diet and cardiovascular disease

Interventions
In a single test meal consisting of a muffin and a milkshake, three test fats (50 g) are compared versus a control fat (high oleic sunflower oil; 50 g). These are; native palm olein , chemically interesterified palm olein and lard.
1. Palm olein represents a palmitic acid-rich fat with palmitic acid almost exclusively (~90%) in the sn-1 and -3 positions
2. Chemically interesterified palm olein represents a palmitic acid-rich fat with a high proportion of palmitic acid in the sn-2 position (~33%)

3. Lard represents an animal fat with a high proportion of palmitic acid in the sn-2 position (~58%)
4. High oleic sunflower oil will be used as a reference oil for the control test meal

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Postprandial changes in plasma glucose (measured at: 0, 15, 30, 60, 90, 120, 150, 180, 240, 300, 360, 420 and 480 minutes) and plasma triacylglycerol concentrations (measured at 0, 60, 120, 180, 240, 300, 360, 420 and 480 minutes). Both will be measured using enzymatic assays.

Secondary outcome measures
1. Apolipoprotein B48 concentrations, measured at 0, 180, 240, 300 and 480 minutes
2. The positional distribution of chylomicron lipids in the sn-2 position, measured at 180, 240 and 300 minutes
3. Non-esterified fatty acids, measured at 0, 60, 120, 180, 240, 300, 360, 420 and 480 minutes
4. Plasma fatty acids, measured at 0, 60, 120, 180, 240, 300, 360, 420 and 480 minutes
5. Total cholesterol, measured at 0, 60, 120, 180, 240, 300, 360, 420 and 480 minutes
6. Insulin, measured at 0, 15, 30, 60, 90, 120, 150, 180, 240, 300, 360, 420 and 480 minutes
7. C-peptide, measured at 0, 15, 30, 60, 90, 120, 150, 180, 240, 300, 360, 420 and 480 minutes
8. Gut hormones (including the incretin, glucose-dependent insulinotropic polypeptide, peptide YY and cholecystokinin), measured at 0, 15, 30, 60, 90, 120, 150, 180, 240, 300, 360, 420 and 480 minutes
9. Cytokines (interleukin-6, tumour necrosis factor alpha, E-selectin), measured at 0, 180, 240, 300 and 480 minutes
10. Factor VII activated concentrations, measured at 0, 180 and 360 minutes

Overall study start date
20/02/2009

Completion date
01/10/2009

Eligibility

Key inclusion criteria
Healthy males and females, aged 18 - 45 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48 participants

Key exclusion criteria
1. A reported history of heart disease, diabetes, cancer, kidney, liver or bowel disease (healthy volunteers are required)
2. Current cigarette smoker
3. History of substance abuse or alcoholism (previous weekly alcohol intake greater than 60 units /men or 50 units/women)
4. Current self-reported weekly alcohol intake exceeding 28 units
5. Unwilling to follow the protocol and/or give informed consent
6. Weight change of greater than 3 kg in preceding 2 months
7. Body mass index (BMI) less than 20 and greater than 35 kg/m^2
8. Blood pressure greater than 160/90 mmHg
9. Fasting blood cholesterol greater than 7.8 mmol/l, fasting plasma triacylglycerol concentrations greater than 3 mmol/l, or fasting plasma glucose greater than 7 mmol/L
10. Presence of gastrointestinal disorder or use of a drug, which is likely to alter gastrointestinal motility or nutrient absorption
11. Greater than or equal to 20% 10-year risk of cardiovascular disease (CVD) as calculated using the risk calculator
12. Vegetarian dietary practices
13. Pregnant women

Date of first enrolment
20/02/2009

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
England

Netherlands

United Kingdom

Study participating centre
Nutritional Sciences Division
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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

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	01/12/2011		Yes	No