

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

<b>Submission date</b> 26/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/02/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Tom Sanders

**Contact details**  
Nutritional Sciences Division  
Franklin Wilkins Building  
150 Stamford Street  
London  
United Kingdom  
SE1 9NH

## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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

Contact details for joint Principal Investigator:

Professor Ronald P. Mensink, PhD

Department of Human Biology

School for Nutrition, Toxicology and Metabolism

Maastricht University

PO Box 616

6200 MD Maastricht

The Netherlands

### **Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

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.

**Key secondary outcome(s)**

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

**Completion date**

01/10/2009

**Eligibility****Key inclusion criteria**

Healthy males and females, aged 18 - 45 years.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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<sup>2</sup>
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**

United Kingdom

England

Netherlands

**Study participating centre**

**Nutritional Sciences Division**

London

United Kingdom

SE1 9NH

## Sponsor information

**Organisation**

King's College London (UK)

**ROR**

<https://ror.org/0220mzb33>

# Funder(s)

## Funder type

Government

## Funder Name

Malaysian Palm Oil Board (MPOB) (Malaysia)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/12/2011		Yes	No