

# The effects of high fat meals enriched with n-3 fatty acids on blood pressure at rest & during exercise

<b>Submission date</b> 21/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/09/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

The acute effects of high fat meals enriched with eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA) versus oleic acid on cardiac output and other cardiovascular haemodynamics at rest and during dynamic exercise in healthy young men

## **Acronym**

FICO

## **Study objectives**

Meals containing long-chain n-3 PUFA derived from fish oil, eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA), would cause a decrease in exercise systemic vascular resistance and attenuate the increase in exercise blood pressure

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Bexley & Greenwich NHS Research Ethics Committee approved the study December 2007 (ref: 07/H0809/54)

## **Study design**

Single blind randomised crossover trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Cardiovascular disease

## **Interventions**

A randomised, crossover intervention study to investigate the effects of high-fat meals (50g fat) containing high-oleic sunflower oil enriched with 5 g of either EPA or DHA, compared to a control high-fat meal (high-oleic sunflower oil only) on cardiovascular haemodynamics at rest and in response to exercise in 22 healthy males. Blood samples were taken and resting measurements of cardiac output, heart rate and BP were measured at baseline (before the meal) and then hourly over a 5-h period following the meal. A standardized 12 min exercise test was then conducted and further samples were taken and measurements made during exercise and post-exercise. There was at least a 1-week washout period between each of the 3 study days.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Blood pressure (with heart rate and cardiac output), was measured at baseline (before the meal), and then 1, 2, 3 and 5 h after the meal, then at 3, 6 9 and 12 min during the 12-min multi-stage cycling protocol of moderate intensity. Then the subjects were allowed to recover from the

exercise in a seated position and further measurements of blood pressure, heart rate and cardiac output were determined at 15, 30 and 45 min post-exercise.

### **Key secondary outcome(s)**

1. A change in arterial stiffness as measured by digital volume pulse (DVP) (stiffness index [SI] and reflection index [RI]) at baseline (before the meal), and then 1, 2, 3 and 5 h after the meal, and then 15, 30 and 45 min post-exercise (after the 12 min cycling protocol). Blood samples were taken for plasma isoprostanes analysis at baseline (before the meal), and then 5 h after the meal, and then immediately post-exercise (after the 12 min cycling protocol).
2. A change in 8-isoprostane-F2alpha concentrations as an index of oxidative stress

### **Completion date**

30/07/2008

## **Eligibility**

### **Key inclusion criteria**

Healthy men, aged 18 - 45 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Male

### **Key exclusion criteria**

1. Current smokers or those smoked in the past 6 months
2. Consumption of more than a portion of oily fish per week and/or regular fish oil supplementation within the past 3 months
3. Body mass index less than 18.0 and greater than 30 kg/m<sup>2</sup>
4. Seated blood pressure of or greater than 140/90mmHg
5. Plasma total cholesterol > 7.8 mmol/L;
6. Plasma triacylglycerol (TAG) >3.0 mmol/L;
7. Diabetes mellitus (fasting plasma glucose >7.0 mmol/L)
8. Abnormal haematology or liver function tests
9. Self-reported history of myocardial infarction, angina, venous thrombosis, stroke, cancer
10. Presence of gastrointestinal disorder or use of a drug, which is likely to alter gastrointestinal motility or nutrient absorption
11. Self-reported weekly alcohol intake of > 28 standard units of alcohol (1 unit = 10 mL ethanol)
12. Systematic use of any kind of drug or prescribed blood pressure anti-inflammatory or blood-thinning medication

**Date of first enrolment**

28/01/2008

**Date of final enrolment**

30/07/2008

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Diabetes and Nutritional Science Division**

London

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## Sponsor information

**Organisation**

King's College London (UK)

**ROR**

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

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Guy's & St Thomas' NHS Foundation Trust in partnership with King's College London (UK) - State Scholarships Foundation (I.K.Y.) & the Department of Health via the National Institute for Health Research (NIHR) comprehensive Biomedical Research Centre award

## 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	01/08/2012		Yes	No