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

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/10/2010	**Overall study status** Completed	
Last Edited 30/09/2013	**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 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
28/01/2008

Completion date
30/07/2008

Eligibility

Key inclusion criteria
Healthy men, aged 18 - 45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
22

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/m2
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
England

United Kingdom

Study participating centre
Diabetes and Nutritional Science Division
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Sponsor information

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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

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	01/08/2012		Yes	No