

# Vascular effects of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA): the MARINA study

<b>Submission date</b> 25/09/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/04/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.medscinet.net/marina/>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Thomas Sanders

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N2041

## **Study information**

### **Scientific Title**

Influence of increasing intakes of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) on vascular function and risk factors for cardiovascular disease

### **Acronym**

MARINA

### **Study objectives**

Increasing the intake of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) will have favourable effects on heart-rate variability, endothelial function, arterial stiffness, blood pressure and these effects will be dose-related.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

St. Thomas' Hospital Research Ethics Committee, 25/02/2008, ref: 08/H0802/3

### **Study design**

Parallel design, double-blind placebo controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

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

Treatment

### **Participant information sheet**

Patient information material can be found at <http://www.medscinet.net/marina/patientinfo.aspx>

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

Cardiovascular disease

### **Interventions**

This is a dietary intervention involving supplementation with encapsulated (n-3) polyunsaturated fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), at three different doses (0.45, 0.9 and 1.8 g/d), compared with olive oil (BP specification) placebo. The duration of

the intervention is 13 months. One month run-in on placebo and 12 months on one of four treatments.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), polyunsaturated fatty acids

**Primary outcome measure**

A change in endothelial function measured by the flow-mediated dilatation technique and ambulatory blood pressure, measured at baseline and 12 months.

**Secondary outcome measures**

1. Heart rate variability, measured at baseline, 6 months and 12 months
2. Arterial stiffness, measured at baseline and 12 months
3. Endothelial progenitor cell number, measured at baseline, 6 months and 12 months
4. Serum lipids, measured at baseline, 6 months and 12 months
5. C-reactive protein, measured at baseline, 6 months and 12 months

**Overall study start date**

01/06/2008

**Completion date**

31/12/2010

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

Men and women, aged 45 - 70 years

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

360

**Key exclusion criteria**

1. A reported history of angina, myocardial infarction or stroke
2. Clinical history of cancer (excluding basal cell carcinoma) in the past five years
3. Uncontrolled type 2 diabetes mellitus (fasting plasma glucose greater than 7 mmol/L)

4. Type 1 diabetes mellitus
5. Chronic renal, liver or inflammatory bowel disease
6. Current cigarette smoker
7. History of substance abuse or alcoholism (previous weekly alcohol intake greater than 60 units /men or 50 units/women)
8. Current self-reported weekly alcohol intake not exceeding 21 units for women and 28 for men
9. Currently pregnant, planning pregnancy or having had a baby in the last 12 months (there are no hazards from the EPA or DHA with regard to pregnancy outcome)
10. Allergy or intolerance to any component of study capsules
11. Unwilling to follow the protocol and/or give informed consent
12. Unwilling to refrain from use of dietary supplements including other sources of fish oil (e.g. cod liver oil)
13. Unwilling to restrict consumption of oily fish
14. Weight change of greater than 3 kg in preceding 2 months
15. Body mass index less than 20 and greater than 35 kg/m<sup>2</sup>
16. Subjects with an overall risk of cardiovascular disease over the next ten years of greater than 20% who have untreated high blood pressure or raised cholesterol (subjects who are on stable medication for blood pressure or serum cholesterol [statins] will be included)

**Date of first enrolment**

01/06/2008

**Date of final enrolment**

31/12/2010

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Nutritional Science Division**

London

United Kingdom

SE1 9NH

## **Sponsor information**

**Organisation**

King's College London (UK)

**Sponsor details**

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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**  
Food Standards Agency (UK) (ref: N2041)

**Alternative Name(s)**  
The Food Standards Agency, FSA

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## **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?
<a href="#">Results article</a>	results	01/10/2011		Yes	No
<a href="#">Results article</a>	genetic analysis results	01/07/2013		Yes	No
<a href="#">Results article</a>	results	01/03/2014		Yes	No