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

Submission date 25/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/12/2008	**Overall study status** Completed	
Last Edited 15/04/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.medscinet.net/marina/

Contact information

Type(s)
Scientific

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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^2
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
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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
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?
Results article	results	01/10/2011		Yes	No
Results article	genetic analysis results	01/07/2013		Yes	No
Results article	results	01/03/2014		Yes	No