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Incorporation of omega-3 fatty acids

Submission date 03/08/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/08/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 17/02/2023	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study to compare the appearance in the blood of two omega-3 fats, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), as a result of the taking supplements providing omega-3 fats in different chemical forms. Our goal is to find out whether the chemical form of the supplement affects the incorporation of the fatty acids into blood fats and blood cells. If the different chemical forms are incorporated to different extents or at different rates this may influence their ability to affect health. Thus this information will be important to consumers, to supplement manufacturers, and to government and other regulatory authorities.

Who can participate?
100 healthy men and women aged 18 to 45 years.

What does the study involve?
Participants will be randomly allocated to take one of five supplements daily for 12 weeks (either omega-3 fats in one of four chemical forms or a placebo [dummy] supplement). Participants will make clinic visits at the start of the study and at weeks 1, 2, 4, 8 and 12. Blood will be collected at each clinic visit. At the end of the study, we will compare the amount of EPA and DHA in the blood and in blood cells in order to see if there is a difference between the supplements.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. There is a very small chance of infection and a chance of bleeding and bruising at the site of insertion of the needle for collecting the blood sample.

Where is the study run from?
University of Southampton (UK).

When is the study starting and how long is it expected to run for?
Study recruitment started in January 2012 and participants were enrolled for 12 weeks.

Who is funding the study?
Vifor Pharma (Switzerland).

Who is the main contact?
Professor Philip Calder
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
RHM NUT0061

Study information

Scientific Title
Incorporation of omega-3 fatty acids from different chemical forms into blood lipid pools in healthy humans

Study objectives
The appearance of Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) in plasma lipids and blood cells will differ according to chemical formulation of the parent oil.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South west Hampshire Research Ethics Committee, 02/06/2011, ref: 11/SC /0049

Study design
Randomised placebo-controlled double-blind parallel study

Primary study design
Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied
Healthy subjects

Interventions
Participants were allocated to one of the following groups:
1. Placebo
2. Omega-3 ethyl esters
3. Omega-3 free fatty acids
4. Omega-3 triglycerides (standard formulation)
5. Omega-3 triglycerides (interesterified formulation)

All forms of supplement provide 1.1 g EPA plus 0.4 g DHA daily. Supplements will be taken orally. The duration of treatment will be 3 months. Blood samples will be taken during supplementation at 0, 1, 2, 4, 8 and 12 weeks.

Intervention Type
Supplement

Primary outcome(s)
Change in EPA content of plasma phospholipids from study entry to week 12

Key secondary outcome(s)
1. Change in EPA content of each of the other plasma lipid pools and of mononuclear cells and red blood cells from study entry to week 12
2. Change in DHA content of each of the plasma lipid pools and of mononuclear cells and red blood cells from study entry to week 12
3. Change over time in blood concentrations of inflammatory markers

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Healthy
2. Aged 18 to 45 years
3. Body mass index 20 to 32 kg/m2
4. Not consuming fish oil or other oil supplements
5. Not eating more than one oily fish meal per week
6. Willing to adhere to the study protocol
7. Being able to provide written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Aged < 18 or > 45 years
2. Body mass index < 20 or > 32 kg/m2
3. Being diabetic (type 1 or type 2)
4. Use of prescribed medicine to control inflammation
5. Chronic gastrointestinal problems (e.g. IBD, IBS, celiac disease, cancer)
6. Allergic to fish
7. Participation in another clinical trial
8. Use of fish oil or other oil supplements

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Vifor Pharma (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised datasets generated during and/or analysed during the current study are available upon request from Philip Calder (pcc@soton.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016		Yes	No
Protocol file	version 2	14/04/2011	16/02/2023	No	No