ISRCTN11656280 https://doi.org/10.1186/ISRCTN11656280

Bioavailability of omega-3 fatty acids

Submission date	Recruitment status	[_] Prospectively registered
21/03/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/02/2023	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Omega-3 fatty acids are essential in the diet, as the body is unable to make them itself (essential fatty acids). Although they can be found in plant sources, the most important omega-3 fatty acids are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are only found in certain types of fish. There are a wide variety of different omega-3 supplements of the market, which provide EPA and DHA in different forms. In this study, the appearance in the blood of EPA and DHA after taking omega-3 fats in different chemical forms will be compared. The aim of this study is to find out whether the chemical form of the supplement affects the way the fatty acids incorporate into blood fats and blood cells.

Who can participate?
Healthy men aged 18 to 45 years.

What does the study involve?
Participants are randomly allocated to five groups, who consume five different omega-3 fat supplements with a standard high fat meal in a random order. The meals are eaten on five separate study visits spaced two weeks apart. At each clinic visit, a blood sample is taken and then the participants are asked to eat the meal (and omega-3). After this, further blood samples are taken 30 minutes, one, one and a half, two, two and a half, three, four, five and six hours after finishing the meal in order to measure levels 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?
October 2009 to September 2010

Who is funding the study?
Vifor Pharma (Switzerland)

Who is the main contact?
Professor Philip Calder
pcc@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Philip Calder

Contact details
Faculty of Medicine
University of Southampton
IDS Building
MP887 Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Additional identifiers

Protocol serial number
RHMNUT0058

Study information

Scientific Title
Bioavailability and disposition of omega-3 fatty acids from different chemical forms

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)
Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee, 04/02/2010, ref: 09/H0501/98

Study design
Randomised blinded single-centre cross-over trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Omega-3 metabolism

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

All forms of supplement provide 1.1 g EPA plus 0.4 g DHA daily. Supplements will be taken orally immediately following consumption of a standard high fat meal. Blood samples will be immediately before the meal and at 0.5, 1, 1.5, 2, 2.5, 3, 4, 5 and 6 h after consuming the meal.

All subjects will consume all five types of supplement in random order and separated by at least two weeks.

Intervention Type
Supplement

Primary outcome(s)
Change in EPA and DHA contents of plasma phospholipids is measured using blood testing at baseline (immediately before the meal) and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5 and 6 hours after consuming the meal

Key secondary outcome(s))
1. Change in EPA content of plasma triglycerides, cholesteryl esters and non-esterified fatty acids, and erythrocytes and mononuclear cells over 6 hours
2. Change in DHA content of plasma triglycerides, cholesteryl esters and non-esterified fatty acids, and erythrocytes and mononuclear cells over 6 hours
3. Change in blood concentrations of inflammatory markers over 6 hours

All secondary outcomes are measured using blood testing at baseline (immediately before the meal) and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5 and 6 hours after consuming the meal.

Completion date
06/09/2010

Eligibility

Key inclusion criteria
1. Male
2. Aged 18 to 45 years

3. In general good health
4. Body mass index between 20 and 32 kg/m2
5. Not consuming fish oil or other oil supplements
6. Not eating more than one oily fish meal per week
7. Willing to adhere to the study protocol
8. 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
Male

Total final enrolment
10

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

Date of first enrolment
21/04/2010

Date of final enrolment
28/04/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Southampton
Faculty of Medicine
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Vifor Pharma

Alternative Name(s)
Vifor Pharma Management Ltd., Vifor Pharma Management AG, Vifor Pharma Management SA, Vifor Pharma Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	01/03/2010	16/02/2023	No	No