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Incorporation of omega-3 fatty acids in healthy humans

Submission date 13/02/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/02/2017	**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

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. Omega-3 fatty acids from foods and from supplements need to be digested in the small intestine. Emulsification is an early part of the digestive process and makes the omega-3 fatty acids more soluble. Limited emulsification may limit omega-3 fatty acid uptake into the body (bioavailability). Conversely pre-emulsification may promote omega-3 fatty acid uptake into the body. A self-microemulsifying drug delivery system (SMEDDS) promotes emulsification after oral consumption. In this study, the appearance in the blood of EPA and DHA will be compared after taking omega-3 fats in emulsified or SMEDDS forms. The aim of this study is to find out whether the self-emulsification of the supplement affects the way the fatty acids incorporate into blood fats and blood cells.

Who can participate?

Healthy men and women aged 18 to 65

What does the study involve?

Participants are randomly allocated to take one of four omega-3 supplements daily for 12 weeks (either emulsified or SMEDDS forms and at different doses). Participants make clinic visits at the start of the study and at weeks 1, 4 and 12. Blood samples are collected at each clinic visit. The amount of EPA and DHA in the blood and in blood cells are compared in order to see if there is a difference between the supplements.

What are the possible benefits and risks of participating?

There is 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?
July 2015 to August 2017

Who is funding the study?
Pronova BioPharma

Who is the main contact?
Prof. Philip Calder

Contact information

Type(s)
Scientific

Contact name
Prof Philip Calder

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTN00715201

Study information

Scientific Title
Incorporation of omega-3 fatty acids in healthy humans following oral dosing of dietary supplements

Study objectives
A self-microemulsifying drug delivery system (SMEDDS) will enhance bioavailability of the omega-3 fatty acids EPA and DHA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Hampshire A Research Ethics Committee, 11/01/2016, ref: 15/SC/0775

Study design
Double-blind randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not availble in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Omega-3 fatty acid supplementation

Interventions
Patients are manually randomised by the hospital research pharmacist to one of four groups:
1. Omega-3 ethyl esters providing 230 mg EPA + 190 mg DHA
2. SMEDDS Omega-3 ethyl esters providing 230 mg EPA + 190 mg DHA
3. Omega-3 ethyl esters providing 90 mg EPA + 300 mg DHA
4. SMEDDS Omega-3 ethyl esters providing 90 mg EPA + 300 mg DHA

Supplements (3/day) will be taken orally before breakfast. Duration of treatment will be three months. Blood samples will be collected at 0 (samples at 0, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12 and 24 hours), 1, 4 and 12 weeks.

Intervention Type
Supplement

Primary outcome measure
Concentration of EPA and DHA in red blood cells, measured by gas chromatography at baseline, 1, 4 and 12 weeks

Secondary outcome measures
Concentration of EPA and DHA in plasma and white blood cells, measured by gas chromatography at baseline, 1, 4 and 12 weeks

Overall study start date

01/07/2015

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Healthy males and females
2. Age 18 to 65 years
3. Body mass index 20 to 35 kg/m2
4. Not consuming fish oil or similar 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
8. Omega-3 index (EPA+DHA in red blood cells_ < 6.5 at screening

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. Being diabetic (type 1 or type 2)
2. Being vegetarian or vegan and unwilling to consume capsules with a beef gelatine coating
3. Use of prescribed medicine to control inflammation
4. Smokers
5. Chronic gastrointestinal problems (e.g. IBD, IBS, celiac disease, cancer)
6. Allergic to fish
7. Allergic to soybean
8. Participation in another clinical trial (currently or in the 12 weeks prior to study entry)
9. Pregnancy or lactation
10. Blood donations during 3 months prior to or during the study period
11. Omega-3 index (EPA+DHA in red blood cells > 6.5 at screening

Date of first enrolment
18/04/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Pronova BioPharma

Sponsor details
Lilleakerveien 2c
Oslo
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0283

Sponsor type
Industry

ROR
https://ror.org/03ccpe393

Funder(s)

Funder type
Industry

Funder Name
Pronova BioPharma

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal (likely 2018)

Intention to publish date
01/08/2018

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	01/11/2018		Yes	No
Protocol file	version 4	27/05/2016	16/02/2023	No	No
HRA research summary			28/06/2023	No	No