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Incorporation of omega-3 fatty acids

Submission date 11/07/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/07/2019	**Overall study status** Completed	
Last Edited 16/02/2023	**Condition category** 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 is 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). The components within some omega-3 supplements may help with the emulsification process. We think that having a mix of glycerides might help in this way. This is what we will test in this study. The appearance in the blood of EPA and DHA will be compared after taking omega-3 fats in two different forms, with one of these being the special mix of glycerides, and the other one being in ethyl ester form which is the common form of many omega-3 supplements today. The aim of the study is to find out whether having the mix of glycerides within an omega-3 supplement affects the way the fatty acids incorporate into blood fats.

Who can participate?
Healthy men and women aged 50 to 70 years

What does the study involve?
Participants will receive two different omega-3 supplements in random order. They will take each supplement on a single occasion separated by about two weeks. They will be fasted when they take each supplement. Blood samples will be collected several times up to 12 hours after taking each supplement. The amount of EPA and DHA in the blood will be compared in order to see if there is a difference between the two 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?
August 2019 to October 2019

Who is funding the study?
BASF AS (Norway)

Who is the main contact?
Prof. Philip Calder
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Contact information

Type(s)
Scientific

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Prof Philip Calder

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CTN800218102

Study information

Scientific Title

Influence of an omega-3 fatty acid triglyceride formulation on EPA and DHA appearance in human plasma after single dosing

Study objectives
An omega-3 supplement containing a mix of glycerides will enhance bioavailability of the omega-3 fatty acids EPA and DHA

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2019, NHS HRA London – Brighton and Sussex Research Ethics Committee (Boardroom, Sussex House, Royal Sussex County Hospital, 1 Abbey Road, Brighton, BN2 1ES; 020 797 22567; NRESCommittee.SECoast-BrightonandSussex@nhs.net), ref: 19/LO/0939

Study design
Double-blind random order cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available 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 to the order in which they will take the two supplements by the hospital research pharmacist. The two supplements are:
1. Omega-3 ethyl esters providing 500 mg EPA + 200 mg DHA
2. Omega-3 glyceride formulation providing 500 mg EPA + 200 mg DHA

The first supplement (4 capsules) will be taken in the fasting state. Blood samples will be collected at 0, 1, 2, 3, 4, 5, 6, 8 and 12 hours. This will be repeated about two weeks later with the second supplement.

Randomisation will be performed by a University Hospital Southampton research pharmacist using the alea system.

Intervention Type
Supplement

Primary outcome measure
Concentration of EPA and DHA in plasma measured by gas chromatography at different time points up to 12 hours

Secondary outcome measures
Tolerability will be assessed simply by monitoring adverse events. Subjects will spend 2 x 12 hour days for clinic visits and adverse events will be monitored across each of these visits.

Overall study start date
01/07/2018

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Healthy males and females
2. Age 50 to 70 years
3. Body mass index 20 to 35 kg/m2
5. Not eating more than one oily fish meal per week
6. Willing to adhere to the study protocol
7. Able to provide written informed consent
8. Omega-3 index (EPA+DHA in red blood cells) ≤ 6.5 at screening visit

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Diabetic (type 1 or type 2)
2. Vegetarian or vegan and unwilling to consume capsules with a beef gelatine coating
3. Use of prescribed medicine to control inflammation
4. Smokers
5. Alcohol consumption > 14 units per week
5. Chronic gastrointestinal problems (e.g. IBD, IBS, celiac disease, cancer)

6. Allergic to fish
7. Use of fish oil or other oil supplement
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

Date of first enrolment
01/08/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southam,pton NHS Foundation Trust
Tremona Road
Southampton
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Sponsor information

Organisation
BASF AS

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Sponsor type
Industry

Website
https://www.basf.com/no/en/who-we-are/BASF-in-Norway.html

ROR
https://ror.org/03ccpe393

Funder(s)

Funder type
Industry

Funder Name
BASF AS (Norway)

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal

Intention to publish date
01/04/2020

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	13/10/2020	14/10/2020	Yes	No
Protocol file	version 3	05/03/2019	16/02/2023	No	No
HRA research summary			28/06/2023	No	No