

# Omega-3 fatty acids and inflammation

<b>Submission date</b> 22/08/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/09/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/02/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims:

We are carrying out a study of 50 healthy normal weight subjects and 50 moderately obese subjects to compare the anti-inflammatory effects of omega-3 fats, to see if they work differently in normal weight and obese people. We will measure inflammatory chemicals in the bloodstream and in fat tissue of the study participants in two different settings.

Who can participate?

The study will recruit 50 normal weight healthy men and women aged 18 to 65 years and 50 moderately obese men and women aged 18 to 65 years.

What does the study involve?

Participants will firstly take part in three clinic visits where they will consume a standard high fat meal or the high fat meal and an omega-3 supplement. The first will be in the first six hours after eating a standard high fat meal or the high fat meal along with an omega-3 supplement. Only blood samples will be collected in this part of the study. The second will be after taking a daily omega-3 supplement of a control supplement for a period of 12 weeks. In this part of the study both blood samples and a small piece of fat tissue from the lower abdomen will be collected. Our goal is to find out whether omega-3 fats have the same anti-inflammatory effects in normal weight and moderately obese people. Finally participants will have another clinic visit to consume the same standard high fat meal as before with collection of blood samples over six hours. The purpose of this is to see if the period of 12 weeks of taking the omega-3 supplement has altered the way the participants respond to the meal. This information will be important to consumers, to supplement manufacturers, and to government and other regulatory authorities.

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 blood samples and the fat tissue.

Where is the study run from?

University of Southampton (UK)

When is study starting and how long is it expected to run for?

January 2012 to June 2016

Who is funding the study?  
European Commission (Belgium)

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Philip Calder

**Contact details**  
University of Southampton  
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## Additional identifiers

**Protocol serial number**  
RHM NUT0062

## Study information

**Scientific Title**  
Omega-3 fatty acids and inflammation in normal weight and obese subjects

### Study objectives

1. The post-prandial inflammatory response will be exaggerated in obese compared with normal weight subjects
2. Marine omega-3 fatty acids with a meal will reduce the post-prandial inflammatory response to a high fat meal in both normal weight and obese subjects
3. Chronic intake of marine omega-3 fatty acids will reduce inflammation in both normal weight and obese subjects
4. Chronic intake of marine omega-3 fatty acids will reduce the post-prandial inflammatory response to a high fat meal in both normal weight and obese subjects

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

## **Study design**

Randomised placebo-controlled double-blind parallel study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Healthy and moderately obese subjects

## **Interventions**

Placebo or marine omega-3 fats (1.8 g/day) to be taken as oral supplements.

In phase 1 the supplements will be taken once with a standard high fat meal and blood samples will be taken after 0, 1,2, 3, 4 and 6 hours.

In phase 2 the supplements will be taken daily during supplementation for 12 weeks. Blood and fat tissue samples will be taken after 0 and 12 weeks.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

1. Blood inflammatory markers (a range of cytokines and chemokines) in response to a standard high fat meal measured by immunoassay at several time points up to 6 hours after the meal
2. Change from week 0 (study entry) in blood inflammatory markers (a range of cytokines and chemokines) measured by immunoassay after 12 weeks of consumption of omega-3 fatty acids or placebo
3. Change from week 0 (study entry) in fat tissue inflammation (infiltrating macrophages measured by immunohistochemistry and inflammatory markers measured as messenger RNA levels by RT-PCR) after 12 weeks of consumption of omega-3 fatty acids or placebo

## **Key secondary outcome(s)**

1. Blood lipids (triglycerides, fatty acids), glucose and various hormones (insulin, incretins) in response to a standard high fat meal measured at several time points up to 6 hours after the meal
2. Blood omega-3 fatty acids in response to a standard high fat meal measured by gas chromatography at several time points up to 6 hours after the meal
3. Change from week 0 (study entry) in blood omega-3 fatty acids measured by gas chromatography after 12 weeks of consumption of omega-3 fatty acids or placebo

## **Completion date**

30/06/2013

## **Eligibility**

### **Key inclusion criteria**

1. Male or female
2. Aged 18 to 65 years
3. Body mass index 18.5 to 25 or 30 to 40 kg/m<sup>2</sup>
4. If body mass index is 30 to 40 kg/m<sup>2</sup> waist circumference is > 94 cm for men or > 80 cm for women
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)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

100

**Key exclusion criteria**

1. Aged < 18 or > 65 years
2. Body mass index < 18.5, 25-29.9 or > 40 kg/m<sup>2</sup>
3. If body mass index is 30 to 40 kg/m<sup>2</sup> waist circumference is < 94 cm for men or < 80 cm for women
4. Diagnosed diabetes
5. Use of prescribed medicine to control inflammation
6. Use of prescribed medication to control blood lipids (e.g. statins, fibrates (fenofibrate), Omacor)
7. Use of prescribed medication to control blood pressure (ACE inhibitors, angiotensin 2 receptor blockers, calcium channel blockers, Ñ-inhibitors, thiozide diuretics)
8. Use of fish oil or other oil supplements
9. Chronic gastrointestinal problems (e.g. IBD, celiac disease, cancer)
10. Pregnant or planning to become pregnant within the study period
11. Participation in another clinical trial

**Date of first enrolment**

01/02/2012

**Date of final enrolment**

24/10/2013

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

University of Southampton

Southampton

United Kingdom

SO16 6YD

## Sponsor information

**Organisation**

University Hospitals Southampton NHS Foundation Trust (UK)

**ROR**

<https://ror.org/0485axj58>

## Funder(s)

**Funder type**

Government

**Funder Name**

European Commission (EU)

**Alternative Name(s)**

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

## Location

# Results and Publications

### Individual participant data (IPD) sharing plan

Some of the datasets generated during and/or analysed during the current study are stored in a publicly available repository (GEO; <https://www.ncbi.nlm.nih.gov/geo/>) under accession code GSE162653 (<https://www.ncbi.nlm.nih.gov/geo/query/acc.cgi?acc=GSE162653>). Other anonymised datasets generated during and/or analysed during the current study are available upon request from Philip Calder ([pcc@soton.ac.uk](mailto:pcc@soton.ac.uk)).

### IPD sharing plan summary

Stored in publicly available repository, Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Effects on lysophospholipid metabolism	01/08/2016		Yes	No
<a href="#">Results article</a>	Obesity-associated tissue remodelling	25/07/2022	15/08/2022	Yes	No
<a href="#">Results article</a>		02/03/2022	16/02/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 3	07/12/2012	16/02/2023	No	No