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Omega-3 fatty acids and inflammation

Submission date
22/08/2012

Recruitment status
No longer recruiting

Registration date
05/09/2012

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 is 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
Berkshire Research Ethics Committee, 02/11/2011, ref: 11/SC/0384

Study design
Randomised placebo-controlled double-blind parallel study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 wil 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 measure
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

Secondary outcome measures

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

Overall study start date
01/01/2012

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/m2
4. If body mass index is 30 to 40 kg/m2 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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
50 normal weight and 50 moderately obese

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/m2
3. If body mass index is 30 to 40 kg/m2 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
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospitals Southampton NHS Fiundation Trust (UK)

Sponsor details
Research & Development Office
Southampton General Hospital
Tremona Road
Southampton

England
United Kingdom
SO16 6YD

Sponsor type
University/education

Website
http://www.uhs.nhs.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, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Results will be published across several papers in peer reviewed journals.

Intention to publish date
31/12/2016

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).

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?
Results article	Effects on lysophospholipid metabolism	01/08/2016		Yes	No
Results article	Obesity-associated tissue remodelling	25/07/2022	15/08/2022	Yes	No
Protocol file	version 3	07/12/2012	16/02/2023	No	No
Results article		02/03/2022	16/02/2023	Yes	No