ISRCTN48398526 https://doi.org/10.1186/ISRCTN48398526

Assessing the impact of escalating fish oil consumption on n-3 polyunsaturated fatty acid (PUFA) content of transport, storage and functional pools

Submission date
21/03/2006

Registration date
28/04/2006

Last Edited
17/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.mrc-hnr.cam.ac.uk/research/research-sections/diet-population-health/dph-projects/fish-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N05065/N05066

Study information

Scientific Title
Assessing the impact of escalating fish oil consumption on n-3 polyunsaturated fatty acid (PUFA) content of transport, storage and functional pools: a randomised controlled trial

Acronym
FISH

Study objectives
This two-centre study will determine the effect of long-chain (LC) n-3 PUFA supplementation on the fatty acid (FA) content of plasma phospholipids, triacylglycerols, cholesteryl esters and non-esterified fatty acids, platelets, erythrocytes, leukocytes and adipose tissue. Relationships between FA status of different pools and differences according to age and gender will be determined. The intervention is capsule based, to maximise compliance, but will provide LC n-3 PUFA as 'portions' in doses designed to mimic oily fish consumption in free-living.

Please note that, as of 16/01/2009, the anticipated end date of this trial has been amended from 31/12/2008 to 28/02/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Suffolk Research Ethics Committee (REC), approved on 06/02/2006 (ref: 05/Q0102/181)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Impact of fish-oil consumption on the fatty acid content of plasma

Interventions

The five treatment groups are:
1. Control group (n = 42)
2. Capsules equivalent to 1 portion of oily fish per week (containing approximately 1.8 g eicosapentaenoic acid [EPA] and 1.5 g docosahexaenoic acid [DHA] per week) (n = 42)
3. Capsules equivalent to 2 portions of oily fish per week (containing approximately 3.6 g EPA and 3.0 g DHA per week) (n = 42)
4. Capsules equivalent to 2 portions of oily fish per week, taken continuously rather than in a 'portion' (containing approximately 3.6 g EPA and 3.0 g DHA per week) (n = 42)
5. Capsules equivalent to 4 portions of oily fish per week (containing approximately 7.2 g EPA and 6.0 g DHA per week) (n = 42)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA)

Primary outcome measure
The primary outcome is plasma docosahexaenoic acid (DHA) status, expressed as a percentage of total plasma fatty acids.

The three primary comparisons (on which sample size has been calculated) are:
1. Differences in plasma DHA status between treatment groups (2 portions versus control group) at 12 months
2. Differences in plasma DHA status between treatment groups (4 portions versus 2 portions group) at 12 months
3. Difference in plasma DHA status between age groups (old versus young) at 12 months

Secondary outcome measures
Current secondary outcome measures as of 17/01/2019:
Secondary comparisons will include gender effects, additional age comparisons and within-group time relationships (i.e. up to 12 months). Additionally, interactions between portions, age, time and gender will be explored.

Secondary outcomes will include DHA status of other fatty acid pools (also expressed as a percentage of the total fatty acid profile); EPA status of fatty acid pools, EPA plus DHA status of fatty acid pools, other fatty acids, adipose tissue lipidome, and plasma markers of inflammation and physiological function including lipid mediators (i.e. oxylipins).

Previous secondary outcome measures:
Secondary comparisons will include gender effects, additional age comparisons and within-group time relationships. Additionally, interactions between portions, age, time and gender will be explored.

Secondary outcomes will include DHA status of other fatty acid pools (also expressed as a percentage of the total fatty acid profile).

Overall study start date

01/05/2006

Completion date
28/02/2009

Eligibility

Key inclusion criteria
Men and women, aged 20-80 years with a body mass index (BMI) in the range 18-35 kg/m2 will be recruited to the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Known diagnosis of diabetes, cancer, cardiovascular disease or other chronic clinical conditions
2. Untreated hypertension
3. Concomitant prescription of anticoagulants, non-steroidal anti-inflammatory drugs (NSAIDS), aspirin, steroids or immunosuppressants
4. Following a special diet, including vegetarians
5. Allergies or intolerance to fish
6. Consumption of oily fish more than once a month
7. Smokers
8. History of substance abuse or alcoholism
9. Pregnant, <1 year post partum or currently planning pregnancy
10. Recent weight change (>2 kg in past 1 month)
11. Planning to change dietary habits, increase physical activity, change body weight, move away from the study centre locality or take a lengthy vacation during the time of the study

Date of first enrolment
01/05/2006

Date of final enrolment
28/02/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Human Nutrition Research
Cambridge
United Kingdom
CB1 9NL

Sponsor information

Organisation
MRC Human Nutrition Research (UK)

Sponsor details
Elsie Widdowson Laboratory
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Sponsor type
Research council

ROR
https://ror.org/050pqs331

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK) (ref: N05065/N05066)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	lipid pool results	01/10/2012		Yes	No
Results article	results on effects of sex and age	01/02/2014		Yes	No
Results article	blood cell and plasma results	01/05/2014		Yes	No
Results article	results on differences in FA distribution between blood cells and plasma	03/08/2015		Yes	No
Results article	results on use of plasma NEFA as a biomarker	14/09/2015		Yes	No
Results article	lipidomics analysis results	01/09/2017		Yes	No