

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	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 28/04/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/01/2019	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Protocol serial number

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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 Years

Upper age limit

80 Years

Sex

All

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**

United Kingdom

England

Study participating centre

MRC Human Nutrition Research

Cambridge

United Kingdom

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Sponsor information

Organisation

MRC Human Nutrition Research (UK)

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

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