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Fish Feeding Study (FFS): The impact of fish and fish oil capsule intake on omega-3 fatty acid status, health and cognitive function of Omani school children of 9-10 years old living in Muscat

Submission date
13/07/2012

Recruitment status
No longer recruiting

Registration date
10/01/2013

Overall study status
Completed

Last Edited
24/11/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There has been a sharp increase in obesity, type 2 diabetes, and cardio-vascular disease in Omani population. Childhood obesity is a strong precursor for adult obesity which in turn is associated with type 2 diabetes and cardio-vascular disease. Moreover, more children are affected by psychiatric disorder such as attention deficit and hyperactivity disorder. Growing evidence suggests that increased consumption of fish and marine products which are the main source of long-chain omega-3 fatty acids have beneficial effect on obesity, cardio-vascular disease and childrens learning and behaviour. In this study, we aim to (a) assess nutritional status (b) investigate the effect of omega-3 fatty acids either by eating more fish or taking omega-3 oil on the lipid profile, body fat, and cognition and behaviour of Omani children.

Who can participate?
Healthy male and female Omani school children of 9-10 years old living in Muscat, Sultanate of Oman.

What does the study involve?
Children will be asked either to eat fish meal or take one capsule of omega-3 fish oil four times a week for 16 weeks. Blood samples obtained before and after the dietary intervention will be assessed for the nutritional status, blood lipid profile, and total blood counts. Similarly, body composition, and cognition and behaviour will be assessed in all children.

What are the possible benefits and risks of participating?
Each participant (childrens parent or guardian) will receive a feedback on their overall nutritional and health status.
There is no risk of participating.

Where is the study run from?
The study has been set up by the Lipidomics and Nutrition Research Centre, Faculty of Life

Sciences and Computing, London Metropolitan University in collaboration with the Ministries of Agriculture and Fisheries Wealth, Health, and Education, and Sultan Qaboos University, Sultanate of Oman. The recruitment, intervention and part of the assessment will be carried out in Muscat, Sultanate of Oman, and some of the biochemical analysis will be conducted at London Metropolitan University.

When is the study starting and how long is it expected to run for?
The study started in September 2012 and will last for two years.

Who is funding the study?
The Ministry of Agriculture and Fisheries Wealth, Sultanate of Oman has provided the funding for the study.

Who is the main contact?
Profession Kebreab Ghebremeskel
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Study website
http://www.londonmet.ac.uk/faculties/faculty-of-life-sciences-and-computing/research/lipidomics-and-nutrition-research-centre/research-projects/current/fish-feeding-study/

Contact information

Type(s)
Scientific

Contact name
Prof Kebreab Ghebremeskel

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

v1

Study information

Scientific Title
The impact of fish and fish oil capsule intake on omega-3 fatty acid status, health and cognitive function of Omani school children of 9-10 years old living in Muscat: a randomised open-label trial

Acronym
FFS

Study objectives
Additional intake of fish or omega-3 oil capsule does not enhance blood docosahexaenoic acid (DHA) level in healthy Omani school children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research and Ethical Review and Approve Committee, Ministry of Health, Sultanate of Oman, 19/06/2012, ref: MH/DGP/R%S/PROPOSAL_APPROVED/8/2012
2. NRES Committee North West - Haydock, UK, 11/10/2012, REC Reference - 12/NW/0760

Study design
Randomised open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Nutritional status

Interventions
Fish Meal Group - Fish lunch (100-150g of fish per serving) 4 times a week

Omega-3 Oil Group - One fish oil capsule which contains 200-250 mg long-chain omega-3 fatty acids 4 times a week

Total duration of intervention: 16 weeks

Intervention Type
Supplement

Primary outcome measure
Red blood cell docosahexaenoic acid (DHA) level at the end of 16 weeks of dietary intervention

Secondary outcome measures
1. Body fat %
2. Full blood counts
3. Blood lipid profile
4. Behaviour and cognitive functions

Measured at the end of 16 weeks of dietary intervention

Overall study start date
01/09/2012

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Male and female children aged 9-10 years who do not have any hereditary or chronic medical condition

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
354

Key exclusion criteria

Children with known hereditary or chronic medical condition which requires medication or suffer from fish or shellfish allergy

Date of first enrolment
01/09/2012

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

Oman

United Kingdom

Study participating centre
Lipidomics and Nutrition Research Centre
London
United Kingdom
N7 8DB

Sponsor information

Organisation
London Metropolitan University (UK)

Sponsor details
Faculty of Life Sciences and Computing
166-220 Holloway Road
London
England
United Kingdom
N7 8DB

Sponsor type
University/education

Website
http://www.londonmet.ac.uk

ROR
https://ror.org/00ae33288

Funder(s)

Funder type
Government

Funder Name
Ministry of Agriculture and Fisheries Wealth (Oman) (Ref. No. 1/3/43)

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