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Fatty Acid Absorption Study

Submission date	Recruitment status	[ ] Prospectively registered
10/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/03/2008	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2002.112

Study information

Scientific Title

Acronym
FAAS

Study objectives
The biochemical importance of dietary lipids to human physiology and nutrition is now firmly established and research continues to show potential health benefits of polyunsaturated fatty acids (PUFAs) and in particular the omega 3 fatty acids from fish and precursors of the same family found in many plant oils. Current UK recommendations advise the public to eat at least two portions of fish every week including one of oily fish, which is rich in omega-3 PUFAs, or take more than 200 mg/day of omega-3 PUFAs. According to the World Health Organization (WHO), one portion should provide an equivalent of 200-500 mg of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). In fact most people in the UK consume considerably less than one portion per week indicating that the recommended levels are not being achieved leaving fish oil supplementation as the most convenient route to augment dietary intake. However, reaching recommended intake levels may require taking several capsules of fish oil per day. An alternative is to use a more palatable version of liquid fish oils presented as a flavoured emulsion, which may offer a more flexible route to achieve the required level of intake.

Approximately 95% of dietary lipids ingested from foods consist of triacylglycerols (TAGs) and lipid digestion is initiated by the action of lingual/gastric lipases which, together with the physical mixing action of the stomach, produces small partially emulsified droplets containing mainly TAGs but also free fatty acids (FFA) and diacylglycerols. Further emulsification together with the action of pancreatic lipase results in the production of 2-monoacylglycerols (sn2-MAG) and free fatty acids and these are incorporated into mixed micelles before passive diffusion into the enterocyte. Once inside the enterocyte the fatty acids with less than 12 carbon atoms pass directly into the hepatic portal vein. However, most dietary fatty acids have a chain length greater than 12 and these are re-synthesised into TAG and incorporated into the chylomicron (CM) family of lipoproteins which are secreted into the lymphatic system and transported to the thoracic lymphatic duct where they enter the circulation. The fatty acid composition of the core of the CM - TAG generally reflects the dietary fatty acid profile, particularly in the first four to six hours postprandial period. The CM-TAG are rapidly hydrolysed by lipoprotein lipase (LPL) releasing between 70 and 90% of the total TAG and leaving CM remnants which are removed from the plasma via low density lipoprotein (LDL) receptors in the liver. There have been conflicting observations that the use of emulsified forms of fish oils in some studies has led to improved digestion and absorption of EPA and DHA with other studies showing no differences in absorption.

Preliminary research in our laboratory has indicated that both the rate and extent of absorption of the fatty acids EPA and DHA improve if the oil is pre-emulsified prior to ingestion. This cross over absorption study was designed to establish whether pre-emulsification of an oil mixture leads to improved absorption of fatty acids, particularly DHA and EPA, compared with the non-emulsified form of the oil mixture.

The hypothesis of this trial is that absorption of fatty acids occurs more rapidly and extensively in a pre-emulsified form than in the straight oil.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received by the local research ethics committee (Lechyd Morgannwg Health) on the 2nd October 2002.

Study design
Randomised cross-over study with oral ingestion of a fatty acid mixture in the form of an oil mixture or a water miscible oil emulsion.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Absorption of fatty acids as part of a healthy dietary lifestyle

Interventions
In a cross-over study, participants were randomly assigned to receive either the oil mixture or oil emulsion mixture, with thirteen subjects receiving oil and eleven subjects receiving oil emulsion in the first stage. The mixtures of oils (comprising concentrated fish oil 43%, borage oil 31% and flaxseed oil 26%) in both the natural form and in the emulsified form were supplied by Cultech Ltd., Port Talbot, United Kingdom.

The participants fasted for 12 hours prior to the study. Subjects consumed 30 ml of oil as part of a meal comprising fat free cereal (37.5 g), skimmed milk (230 ml), sugar (4 g) and apple juice (150 ml). For the remainder of the nine hour collection period the participants ate only boiled rice (100 g), boiled pasta (100 g) and fresh fruit (large apple). Apple juice or water was available to drink throughout the day. The average energy intake was 3596 kJ (859 kcal) comprising 147 g carbohydrate, 23 g protein and 32 g total fat. Twenty days later (washout period), the procedure was repeated with the assignments reversed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Plasma fatty acid concentrations.

Secondary outcome measures
No secondary outcome measures

Overall study start date
14/02/2003

Completion date
28/02/2003

Eligibility

Key inclusion criteria
1. Healthy volunteers, male or female
2. Body mass index (BMI) less than 30
3. Capable of providing written informed consent
4. Not pregnant or subject to medication

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Involved in dietary control
2. Obese/very low body weight
3. Hypercholesterolemic
4. Taking dietary fatty acid supplements

Date of first enrolment
14/02/2003

Date of final enrolment
28/02/2003

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Obsidian Research Limited
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Sponsor information

Organisation
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Funded in-house by Cultech Limited with financial support from Welsh Development Agency as part of Technology Exploitation Programme (UK)

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	Results	25/01/2007		Yes	No