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The docosahexaneoic acid (DHA) Oxford Learning and Behaviour (DOLAB) Study

Submission date	Recruitment status
20/02/2009	No longer recruiting
Registration date	**Overall study status**
07/04/2009	Completed
Last Edited	**Condition category**
12/06/2015	Nutritional, Metabolic, Endocrine

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

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
NCT01066182

Secondary identifying numbers
08/H0603/49

Study information

Scientific Title
The docosahexaneoic acid (DHA) Oxford Learning and Behaviour (DOLAB) Study: a randomised double-blind placebo-controlled trial

Acronym
DOLAB

Study objectives
We hypothesise that docosahexaneoic acid (DHA) (in a daily dose of 600 mg) will improve the behaviour and learning of normal children aged 7 - 9 years in mainstream state schools who are underperforming according to nationally standardised tests.

Please note as of 13/12/2011 the target number of participants were modified. Previously target number of participants: 360

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Milton Keynes Research Ethics Committee, 08/12/2008, ref: 08/H0603/49

Study design
Randomised double-blind placebo-controlled trial

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 provided in the Interventions field to request a patient information sheet

Health condition(s) or problem(s) studied
Learning and behaviour in children

Interventions
The active intervention will consist of 3 x 500 mg capsules per day orally, each capsule providing 200 mg of DHA as a triglyceride. The liquid fill contains DHASCO®-S oil derived from the microalgae Schizochytrium sp., high-oleic sunflower oil, natural mixed tocopherols, ascorbyl

palmitate, and rosemary extract (flavouring). The gelatin shell contains glycerin, water, and colouring (carmel, carmine, turmeric).

The placebo will consist of 3 x 500 mg capsules per day orally containing high-oleic sunflower oil. The dimensions, taste, appearance and colour will be identical to those of the DHA capsules. The shell of the capsule will be the same as the DHA capsule. The liquid fill contains high-oleic sunflower oil, natural mixed tocopherols, ascorbyl palmitat and rosemary extract (flavouring).

Duration of interventions: 16 weeks

Please use the following contact details to request a patient information sheet:
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Docosahexaneoic acid (DHA) (DHASCO®-S)

Primary outcome measure
Children's age-standardised scores for behaviour (teacher ratings of attention deficit hyperactivity disorder [ADHD]-type symptoms) and learning (reading performance and working memory), assessed post-intervention. The following validated measures will be used:
1. Conners Teacher and Parent Ratings (CTRS-L and CPRS-L)
2. British Ability Scale (BAS II): Word reading
3. British Ability Scale (BAS II): Recall of Digits

Secondary outcome measures
Correlations between changes in omega-3 (DHA) status and the primary outcomes plus any post-intervention changes in sleep (Combined Sleep Disturbance Index, and in 10% subset monitored objectively with actigraphy, sleep latency and duration).

Overall study start date
01/03/2009

Completion date
24/10/2011

Eligibility

Key inclusion criteria
1. Children (both males and females) aged 7 - 9 years from mainstream state schools who are underperforming in literacy skills according to nationally standardised assessments of scholastic achievement at age 7 years (Key Stage 1). To be eligible, children must score below the 33rd centile for reading/writing, but within the normal range in at least one other domain.
2. English as a first language

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
360

Key exclusion criteria
1. Major learning disabilities or medical disorders
2. Taking medications expected to affect behaviour and learning
3. Taking fish oils already, or eating fish two times or more a week

Date of first enrolment
01/03/2009

Date of final enrolment
24/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Evidence Based Intervention
Oxford
United Kingdom
OX1 2ER

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Martek Biosciences Corporation (USA)

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	01/03/2012		Yes	No