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

Submission date	Recruitment status	Prospectively registered	
20/02/2009	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
07/04/2009	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
12/06/2015	Nutritional, Metabolic, Endocrine		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paul Montgomery

Contact details

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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:
Jenny Burton
The DOLAB Study
Centre for Evidence Based Intervention
Barnett House
32 Wellington Square
Oxford
OX1 2ER
United Kingdom
Tel: +44 (0)1865 270320

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

E-mail: jennifer.burton@socres.oxac.uk

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 John Radcliffe Hospital Oxford England United Kingdom OX3 9DU +44 (0)1865 222757 heather.house@admin.ox.ac.uk

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 summaryNot 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