

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

Submission date 20/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/04/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/06/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

ClinicalTrials.gov (NCT)
NCT01066182

Protocol serial number
08/H0603/49

Study information

Scientific Title

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

Acronym

DOLAB

Study objectives

We hypothesise that docosahexaneic 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

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

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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The DOLAB Study

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Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Docosahexaneic acid (DHA) (DHASCO®-S)

Primary outcome(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 Years

Upper age limit

9 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Centre for Evidence Based Intervention

Oxford

United Kingdom

OX1 2ER

Sponsor information**Organisation**

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Industry

Funder Name

Martek Biosciences Corporation (USA)

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	results	01/03/2012		Yes	No