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Optimising nutrition to improve growth and reduce neurodisabilities in children with suspected or confirmed cerebral palsy

Submission date 23/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/04/2010	**Overall study status** Completed	
Last Edited 05/01/2016	**Condition category** Nervous System Diseases	

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
6797

Study information

Scientific Title
Optimising nutrition to improve growth and reduce neurodisabilities in children with suspected or confirmed cerebral palsy: a randomised interventional treatment trial

Acronym
Dolphin Study 2

Study objectives
The purpose of this study is to identify as early as possible children with a suspected or confirmed clinical diagnosis of cerebral palsy, defined as:
'A group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to nonprogressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour, by epilepsy, and by secondary musculoskeletal problems.'

We will then institute a nutritional care programme that ensures optimal macro- and micro-nutrient intake over a critical period of brain development.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee B, 12/01/2009, ref: 08/H0605/155

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Neurological, Generic Health Relevance and Cross Cutting Themes; Subtopic: Neurological (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Nervous system disorders, Paediatrics

Interventions
The intervention is in the form of a neurotrophic supplement containing docosahexanoic acid (DHA), uridine monophosphate (UMP) and choline, along with supportive vitamins and minerals. The control being used is an iso-caloric, iso-nitrogenous placebo substance. The active supplement or control will be taken once daily and added to feed or food. This can be taken orally or via a feeding tube and supplementation will continue for the whole 2 years of the study. Follow Up Length: 24 month(s).

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Docosahexanoic acid (DHA), uridine mono-phosphate (UMP), choline, vitamins, minerals

Primary outcome measure
Neurodevelopmental outcome which will be assessed using the Bayley Scale of Infant Development performed at baseline and at 12 and 24 months in to the study.

Secondary outcome measures
1. Growth: assessed using anthropometry carried out every 3 months (weight, height, skinfold measurements and head circumference)
2. Electrophysiology: Visual Evoked Potential and behavioural vision testing tested at baseline, 12 months post term, 24 months post term, 42 months post term
3. Neuroimaging: changes of brain biochemistry and choline uptake as estimated by MRS once at the end of the study
4. Indices of general health status: Prevalence of epilepsy, feeding difficulties, clinically significant gastro-oesophageal reflux, constipation, number of chest infections (requiring antibiotics) and hospital admissions to be assessed every 3 months
5. Corticospinal axon diameter: assessed by transcranial magnetic stimulation and will be done at baseline and at the end of the study

Overall study start date
01/12/2008

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Children between the ages of 6 to 18 months, either sex
2. Suspected or confirmed clinical diagnosis of cerebral palsy as defined below:
'A group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to nonprogressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by

disturbances of sensation, perception, cognition, communication, and behaviour, by epilepsy, and by secondary musculoskeletal problems.'
3. Parent or guardian who is willing to sign the consent form

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
18 Months

Sex
Both

Target number of participants
Planned Sample Size: 60

Key exclusion criteria
1. Children with progressive neurological degenerative conditions
2. Children with significant gastrointestinal disease
3. Parents considered by clinicians to be unable to follow the study protocol

Date of first enrolment
01/12/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Clinical Trials and Research Governance (UK)

Sponsor details
Oxford University
Oxford University Research Services
Manor House
John Radcliffe Hospital
Oxford
England
United Kingdom
OX3 9DU

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Sparks (UK)

Alternative Name(s)
Sparks Charity

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Protocol article	protocol	17/03/2015		Yes	No