

Fish oil-based lipid emulsion decrease inflammation and bronchopulmonary dysplasia in extremely premature infants

Submission date 07/09/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/06/2018	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Preterm infants have significantly lower long chain polyunsaturated fatty acids (LC-PUFA) concentrations than full term infants because they miss the major period of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) development in the brain and other organs during the third trimester of pregnancy. LC-PUFA play a potentially significant role in the modulation (control) of developmental processes affecting short- and long-term health outcomes related to growth, body composition, immune and allergic responses, and nutrition-related chronic disease. The most widely used formulation for parenteral (intravenous) nutrition (PN) is a soybean oil-based lipid emulsions (LE), which is rich in n-6 LC-PUFA and phytosterols which may cause liver toxicity and inflammation. LC-PUFAs (EPA and DHA) from fish oil may prevent the inflammatory response and even reduce any inflammation that exists. Early fish oil-based lipid emulsion (LE) administration to very low birth weight premature infants may reduce the development of chronic lung disease (CLD) and liver dysfunction by decreasing inflammatory cytokines (small signalling proteins) with IL-1 β and IL-6 levels (suggesting inflammation) in serum (a component of the blood) and bronchoalveolar lavage fluid (fluid from the lungs). The aim of this study is to investigate whether this is the case.

Who can participate

Very low birth weight (VLBW) premature infants with a birth weight <1250gm or gestation age <32 weeks.

What does the study involve

Participants are randomly allocated into one of two groups. Those in group 1 are given total parenteral nutrition (TPN) containing a fish oil-based lipid emulsion. Those in group 2 are given TPN containing conventional soybean lipid emulsion. Treatment starts within 48 hours of birth and lasts for at least seven days. The dose starts at 1gm/kg but then increases by 1gm/kg per day until the maximum dose of 3gm/kg.

What are the possible benefits and risks of participating
The treatment may reduce the development of lung and liver problems by reducing inflammation

Where is the study run from
Changhua Christian Hospital (Taiwan)

When is study starting and how long is it expected to run
March 2012 to February 2014

Who is the main contact
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
101-CCH-IRP-15

Study information

Scientific Title
Fish oil-based lipid emulsion attenuates inflammatory cytokines and development of bronchopulmonary dysplasia in extremely premature infants: a randomised controlled trial

Study objectives

The aim of this study to is investigate whether giving preterm infants an early supply of long chain polyunsaturated fatty acids (LC-PUFA) and fish oil-based lipid emulsions (LE) containing ω -3 LC-PUFAs helps prevent the development of bronchopulmonary dysplasia (BPD) by modulating inflammation and neonatal immune function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Changhua Christian Hospital Institutional Review Board Committee A, 22/12/2011, ref: CCH-IRB-110909

Study design

Randomised controlled 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Insufficient docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in premature babies

Interventions

Sixty very low birth weight (VLBW) premature infants were randomized to 2 groups:

1. Study group received total parenteral nutrition (TPN) containing fish oil-based lipid emulsion (SMOF lipid contain 30% soybean-LCT, 30% MCT, 25% olive oil and 15% fish oil).
2. Control group received TPN containing conventional soybean lipid emulsion (Lipovenoes MCT 20%).

Treatment was started within 48 hours of birth and then for at least the next 7 days. The dose of both lipid emulsions were 1 gm/kg at first day of TPN, increasing to 1 gm/kg per day until 3 gm /kg. Macronutrients were provided using the same products for glucose and amino acid solutions in both groups. The premature infant was fed by NG tube or bottle with breast milk or premature formula milk if breast milk was not enough.

Intervention Type

Supplement

Primary outcome measure

Comparison of immune effects of Interleukin (IL)-1 β and IL-6, assessed on the first 48 hours and 7 days after TPN use, including serum IL-1 β and IL-6 and bronchoalveolar lavage fluid from tracheal aspiration if intubated infants. The levels of cytokines in the serum and bronchoalveolar lavage fluid were estimated by enzyme-linked immunosorbent assay.

Secondary outcome measures

1. Mortality
2. Ventilator use days
3. Oxygen dependent days
4. Length of hospital stay (LOS)
5. Growth rate
6. Liver function
7. Parenteral nutrition associated cholestasis (PNAC)
8. Bronchopulmonary dysplasia (BPD)
9. Retinopathy of prematurity(ROP)
10. Necrotizing enterocolitis (NEC)
11. Intraventricular hemorrhage (IVH)
12. Nosocomial infection

Follow up program will finish when the infant is discharged.

Overall study start date

01/03/2012

Completion date

28/02/2014

Eligibility**Key inclusion criteria**

PVLBW infants who weighed below 1250 gm and gestational age below 32 weeks

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Chromosomal disorders or lethal congenital abnormalities
2. Congenital cyanotic heart disease

3. Anatomic obstructive gastrointestinal pathologies, such as intestinal malrotation with or without volvulus, stenosis, or atresia, gastroschisis, omphalocele and Hirschsprung's disease
4. Confirmed or family history of hereditary metabolic disorder

Date of first enrolment

01/03/2012

Date of final enrolment

25/02/2014

Locations

Countries of recruitment

Taiwan

Study participating centre

Changhua Christian Hospital

Taiwan

500

Sponsor information

Organisation

Changhua Christian Hospital

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05d9dtr71>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Changhua Christian Hospital

Alternative Name(s)

CCH

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Taiwan

Results and Publications

Publication and dissemination plan

November 2015. Will submit to BMJ

Intention to publish date

30/11/2015

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019		Yes	No