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

**Submission date**
07/09/2015

**Recruitment status**
No longer recruiting

**Registration date**
15/09/2015

**Overall study status**
Completed

**Last Edited**
27/06/2018

**Condition category**
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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-1β 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
Chien-Chou Hsiao
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### Protocol serial number
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

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Insufficent 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(s)
Comparison of immune effects of Interleukin (IL)-1β and IL-6, assessed on the first 48 hours and 7 days after TPN use, including serum IL-1β 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.

## Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### 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

**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

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |