ISRCTN30731416 https://doi.org/10.1186/ISRCTN30731416

Effects of an optimal omega-3 dose on fatty acids concentrations of breast milk erythrocyte phospholipids in mothers who delivered prematurely: effect on immature preterm infants' fatty acid

Submission date	Recruitment status	[ ] Prospectively registered
19/04/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/06/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/10/2021	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Isabelle Marc

Contact details
Hôpital St-François d'Assise-CHUQ
Centre de recherche
10, rue de l'Espinay
Local D6-705
Quebec
Canada
G1L 3L5
+1 418 525 4348
isabelle.marc@crsfa.ulaval.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAM 06-322

Study information

Scientific Title
Effects of an optimal omega-3 dose on fatty acids concentrations of breast milk erythrocyte phospholipids in mothers who delivered prematurely: effect on immature preterm infants' fatty acid

Acronym
DHA_VPI (DocosaHexaenoic Acid [DHA] for Very Premature Infants)

Study objectives
Our hypothesis is that because most Canadians consume a diet poor in oily fish, supplementation with Docosahexaenoic Acid (DHA)-rich algal oil of the Canadian breast-feeding mothers who deliver prematurely is necessary to obtain optimal DHA in breast-milk and to support the nutritional needs of very premature infants, particularly for brain development.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Comité d'éthique de la recherche clinique du CHUL, Centre Hospitalier Universitaire de Québec [CHUQ]) in March 2007.

Study design
A randomised, double-blind, placebo-controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nutrition of very premature infants

Interventions
An appointment will be scheduled for eligible women, where inclusion and exclusion criteria and risks and benefits of the study will be reviewed in detail and an informed consent form will be signed. A fish consumption questionnaire will be completed by the mother to evaluate dietary intake of fish within the last three months.

Up to 72 hours post delivery, consenting eligible women will be stratified and randomised to receive DHA-rich algal oil 500 mg-capsules (containing DHA 200 mg/cap) or placebo (sunflower oil). The experimental product will be the DHA-rich algal oil DHASCO® (Martek Biosciences Corporation, MD, USA). Two capsules will be taken three times per day before meals for a daily intake of 1.2 g DHA. Placebo and experimental capsules will be provided by Martek Biosciences Corporation to cover a period of at least 12-week supplementation. The DHASCO® brand algal oil is high quality product with little or no after-taste. The experimental product will have the same appearance and levels of vitamin E as the placebo.

Mothers will express breast-milk with an electrical pump from both breasts using a sterile glass sucker. The premature infants will be given daily fresh breast-milk as soon as possible. Trophic feeding will be initiated within 24 to 48 hours in stable preterm infants at 1 mL every four hours if birth weight was less than 1000 g or 2 ml every four hours if birth weight was greater than 1000 g. Initial advancement from day three to five will be of 1 ml every two hours and 2 ml every two hours, respectively.

Further progression will aim at the rate of 20 ml/kg/day, according to feeding tolerance. Feeding intolerance will be defined as residuals greater than 50% of previous feeds in two out of three consecutive feeds and/or persistent abdominal distension, vomiting or diarrhoea. Infants who will receive indomethacin or will be clinically unstable may have a delay in the progression of the feeding independent of their feeding tolerance.

e-Baby sampling time:
We extracted some data from six charts of very premature babies randomly selected among those born in the last year at the Mother and Child Centre (Centre Mere-Enfant [CME]) (CHUQ) in order to provide useful information concerning dietary intake in this population, timing (days postpartum) of the first feeding on breast milk, the delay to the full enteral feeding (140 ml/kg), and growth velocity.

Based on these records we decided that the time of sampling would be:
1. Post-natal Day 3: baseline (before the beginning of enteral feeding)
2. Post-natal Day 14: to observe if the DHA level in plasma and erythrocyte of premature infants will be higher in the group whose mothers received DHA supplementation than in the placebo group. This will permit detection of whether DHA supplementation could avoid the decline in plasma and red cell DHA that has previously been reported at Day 14
3. Post-natal Day 49: will be equivalent to 31 to 36 week post conception of the premature infant. A mean of 31 days to reach full enteral feeding (140 ml/kg) noted in our charts is consistent with a recent study. So, Day 49 will be around the 15th day of full enteral feeding

Finally, at Week 37 post-conception, an extra sampling will permit to compare all the premature infants at the same post-conceptional age (fully mature).

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Docosahexaenoic Acid (DHA)-rich algal oil

Primary outcome measure
Fatty acid composition of the red blood cell membranes and plasma phospholipids of infants will be given as % weight of total fatty acids (qualitative) and in mg/dl (quantitative). There are several fatty acids in the omega-3 series, but the primary outcome will be the difference in the DHA in red cell and plasma phospholipids between the two groups at the 49th day postpartum. Blood samples (0.5 ml) will be obtained at the time of sampling for medical need if matching with our post-natal day 3, 14, 49 and post-conceptional week 37.

Secondary outcome measures
Fatty acid composition of mothers breast-milk will be measured to document the lipid content and the % DHA in the colostrum (at baseline). At the time of the first sampling, mothers will have been nursing for no more than three days. Then every week, sample of breast-milk will be analysed. In order to avoid day-to-day variations, aliquots (0.5 ml) from each daily sample of breast-milk will be pooled weekly, and the combined milk will be analysed to obtain a more representative breast-milk fatty acid profile of the week. Fatty acid composition of mother red cell, taken at the same dates of the premature baby samplings will be related to breast-milk composition.

Overall study start date
01/06/2007

Completion date
15/06/2009

Eligibility

Key inclusion criteria
1. Wowen between 18 and 40 years old
2. Have delivered prematurely (gestional age less than 29 weeks)
3. Plan to breast-feed
4. Signature of consent form for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex

Female

Target number of participants
25 premature infants per group

Key exclusion criteria
Mothers will be excluded if at the time of recruitment they have:
1. Regularly consumed more than three servings/wk of fish in the last three months
2. Regularly consumed omega-3 supplements in the last three months
3. Fish allergy
4. Maternal age at time of delivery less than 18 or more than 40 years
5. Haemostatic or coagulation disease or taking anticoagulants (warfarin, heparin), because of risk of interaction with omega-3
6. History of drug or alcohol abuse
7. Unable to stay at Québec city during the baby hospitalisation

Infants will be excluded if they:
1. Are small for gestational age (less than or equal to third percentile)
2. Have a chromosomal abnormality or major congenital malformations (heart excluding ductus arteriosus, atrial septal defect and small ventricular septal defect, brain abnomalities, gastroschisis, omphalocele, diaphragmatic hernia)

Date of first enrolment
01/06/2007

Date of final enrolment
15/06/2009

Locations

Countries of recruitment
Canada

Study participating centre
Hôpital St-François d'Assise-CHUQ
Quebec
Canada
G1L 3L5

Sponsor information

Organisation
Foundation of the University Hospital Centre of Quebec (CHUQ) (Canada)

Sponsor details

Hôpital St-François d'Assise
10, de l'Espinay Street
Quebec
Canada
G1L 3L5
-
danielle.laprise@crsfa.ulaval.ca

Sponsor type
Hospital/treatment centre

Website
http://www.chuq.qc.ca/fr/

Funder(s)

Funder type
Charity

Funder Name
SickKids Foundation (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration