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Comparison of soybean oil-based versus fish-oil containing lipid emulsions on parenteral nutrition induced cholestatic jaundice in premature infants

Submission date 12/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/11/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/11/2010	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Comparison of soybean oil-based versus fish-oil containing lipid emulsions on parenteral nutrition induced cholestatic jaundice in premature infants: a randomised controlled study

Study objectives
Fish-oil containing lipid emulsions can reduced parenteral nutrition induced cholestatic jaundice in premature infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Khonkaen University Ethics committee for human research approved on the 8th of September 2010 (ref: HE531238)

Study design
Randomised double blind controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parenteral nutrition induced cholestatic jaundice in premature infants

Interventions
1. Control group : Patients were administered parenteral nutrition with a soybean oil-based supplement (Intralipid)
2. Study group : Patients were administered parenteral nutrition with fish-oil containing lipid emulsions (SMOF)
Patients in both groups received fat 0.5-3.5 gm/kg/day daily for 2 weeks. Parenteral nutrition was administered until full feeding was achieved.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Total bilirubin and direct bilirubin.
All outcomes will be assessed at baseline and at 2 weeks after start parenteral nutrition and then follow up weekly until stop parenteral nutrition.

Key secondary outcome(s))
1. Alanine Aminotransferase (ALT)
2. Aspartate Aminotransferase (AST)
3. Alkaline Phosphatase (ALP)
All outcomes will be assessed at baseline and at 2 weeks after start parenteral nutrition and then follow up weekly until stop parenteral nutrition.

Completion date

31/12/2010

Eligibility

Key inclusion criteria
1. Preterm < 34 weeks of gestational age who admitted to NICU and sick newborn ward at Srinagarind hospital
2. Post natal age not more than 1 month
3. Meet indication for parenteral nutrition
4. Parent permitted to be the participant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Risk for bleeding tendency: Platelet less than 60,000 /mm3, coagulopathy
2. Risk for hepatic dysfunction: severe birth asphyxia
3. Fatal chromosome abnormality (Trisomy 13, 15, 18)
5. Direct bilirubin more than 2 mg/dl before start experiment

Date of first enrolment
01/10/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Thailand

Study participating centre
Department of Pediatrics
Khon Kaen
Thailand
40002

Sponsor information

Organisation
Khon Kaen University (Thailand)

ROR
https://ror.org/03cq4gr50

Funder(s)

Funder type
University/education

Funder Name
Khon Kaen University (Thailand) - Faculty of medicine research grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration