

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	<input type="checkbox"/> Prospectively registered
Registration date 25/11/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/11/2010	Condition category Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ratchaneewan Sinitkul

Contact details
Department of Pediatrics
Faculty of Medicine
123 Mitarparp Road
Amphoe Muang
Khon Kaen
Thailand
40002

Additional identifiers

Protocol serial number
N/A

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