

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

<b>Submission date</b> 12/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/11/2010	<b>Condition category</b> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## 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 below to request a patient information sheet

## 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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/10/2010

**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

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

60 participants

**Key exclusion criteria**

1. Risk for bleeding tendency: Platelet less than 60,000 /mm<sup>3</sup>, 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)

**Sponsor details**

Research Affairs

Faculty of Medicine

123 Mitarparp Road

Amphoe Muang

Khon Kaen

Thailand

40002

**Sponsor type**

University/education

**Website**

[http://www.md.kku.ac.th/research/index.php?option=com\\_contact&Itemid=3](http://www.md.kku.ac.th/research/index.php?option=com_contact&Itemid=3)

**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**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration