

# Nutritional Evaluation and Optimisation in Neonates

<b>Submission date</b> 28/10/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/05/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sabita Uthaya

**Contact details**  
Chelsea and Westminster Hospital  
3rd Floor  
Lift bank B  
369 Fulham Road  
London  
United Kingdom  
SW10 9NH

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2009-016731-34

**Protocol serial number**  
EME 08/99/04; CRO1413

## Study information

**Scientific Title**

Amino acid regimen and intravenous lipid composition in preterm parenteral nutrition: a randomised controlled trial of Nutritional Evaluation and Optimisation in Neonates

## **Acronym**

NEON

## **Study objectives**

Introduction of recommended daily intake (RDI) of amino acids will lead to an increase in non-adipose (lean) body mass; administration of SMOFLIPID® will reduce intrahepatocellular lipid content (IHCL) in preterm babies at term age equivalent.

Link to EME project website: <http://www.eme.ac.uk/projectfiles/089904info.pdf>

Protocol can be found at: <http://www.eme.ac.uk/projectfiles/089904protocol.pdf>

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Hammersmith Research Ethics Committee, 08/12/2009

## **Study design**

Multicentre randomised 2 x 2 factorial double-blind controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Preterm birth

## **Interventions**

Eligible preterm infants will be randomised by 24 hours of age (previously 12 hours of age, updated 02/07/2013) to receive:

1. Either incremental amino acids in parenteral nutrition or the RDI of amino acids from day one, and
2. Either 20% intralipid or 20% SMOFLIPID®

There will be four groups:

Group 1: incremental amino acid and 20% intralipid

Group 2: incremental amino acid and 20% SMOFLIPID®

Group 3: RDI of amino acids and 20% intralipid

Group 4: RDI of amino acids and 20% SMOFLIPID®

Infants will be followed from birth and until they reach 37 - 44 weeks corrected age at which point the final study assessment (magnetic resonance imaging [MRI] scan) takes place.

## **Intervention Type**

Supplement

### **Primary outcome(s)**

1. For the amino acid intervention: non-adipose (lean) body mass measured by whole body MRI at term age equivalent
2. For the lipid intervention: hepatic magnetic resonance spectroscopy (MRS) to measure IHCL at term age equivalent

### **Key secondary outcome(s)**

1. Anthropometry (weight, length and head circumference) measured at term age equivalent
2. Brain MRI (brain volumes, white matter apparent diffusion co-efficient values, cerebral vessel tortuosity) measured at term age equivalent
3. Metabolic index of insulin resistance at term age equivalent (quantitative insulin-sensitivity check index [QUICKI]), calculated using fasting serum glucose and insulin

Added 07/12/2009:

4. Ratio of internal to subcutaneous adipose tissue at term age equivalent.
5. Serum triglyceride and serum bilirubin levels.

Added 11/05/2010:

6. Metabonomic profile
7. Incidence of death
8. Number of infants with incomplete follow-up

Added 24/03/2011:

9. Inflammatory markers and lipid profile

### **Completion date**

31/12/2013

## **Eligibility**

### **Key inclusion criteria**

1. Preterm infants (either sex) born below 31 weeks of gestation (defined as less than or equal to 30 weeks and 6 days)
2. Written informed consent from parents

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Neonate

### **Sex**

All

### **Key exclusion criteria**

1. Major congenital or life threatening abnormalities
2. Inability to randomise in time to allow administration of trial parenteral nutrition (PN) within 24 hours of birth

**Date of first enrolment**

20/05/2010

**Date of final enrolment**

31/12/2013

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Chelsea and Westminster Hospital**

London

United Kingdom

SW10 9NH

## Sponsor information

**Organisation**

Imperial College London (UK)

**ROR**

<https://ror.org/041kmwe10>

## Funder(s)

**Funder type**

Government

**Funder Name**

Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme (ref: EME 08/99/04)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2016		Yes	No
<a href="#">Results article</a>	results	01/06/2016		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes