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Nutritional Evaluation and Optimisation in Neonates

Submission date	Recruitment status	[X] Prospectively registered
28/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/05/2016	Pregnancy and Childbirth	

Plain English Summary
Not provided at time of registration

Study website
http://www.rbht.nhs.uk/research/cteu/projects/neonatal-medicine/neon/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-016731-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
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 measure
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

Secondary outcome measures
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

Overall study start date
20/05/2010

Overall study end date
31/12/2013

Eligibility

Participant 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

Age group
Neonate

Sex
Both

Target number of participants
160 infants

Participant 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

Recruitment start date
20/05/2010

Recruitment end date
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Chelsea and Westminster Hospital
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
South Kensington
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
http://www3.imperial.ac.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No
Results article	results	01/06/2016		Yes	No