ISRCTN76597892 https://doi.org/10.1186/ISRCTN76597892

Standardised, Concentrated and Additional Macronutrients in neonatal Parenteral nutrition study

Submission date 23/04/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/05/2009	**Overall study status** Completed	
Last Edited 27/11/2023	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
LWH 0776

Study information

Scientific Title
Standardised, Concentrated, Additional Macronutrients, Parenteral (SCAMP) nutrition in very preterm infants: a phase IV randomised, controlled study of macronutrient intake, growth and other aspects of neonatal care

Acronym
SCAMP

Study objectives
Maximising the macronutrient content of the standardised, concentrated neonatal parenteral nutrition formulation will improve head growth in very preterm infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Manchester Research Ethics Committee, North West Strategic Health Authority. Approval expected on 11/05/2009 (ref: 09/H1008/91).

Study design
Phase IV randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Head growth in very preterm infants

Interventions
Informed consent and randomisation to the trial. Intravenous administration of either scNPN (standard) or scNPNmax (study) solution. Daily collection of routine biochemical monitoring data and all oral and intravenous fluid/drug administration on the case report form. All infants will be measured for weight, lower leg length, occipito-frontal circumference and length on day 0 (baseline) day 7,14,21,28. The total duration of interventions will be until the infant is 28 days old. The follow up will consist of weekly growth measurements until the infant reaches 36/40 post conceptual age and then neuo-developmental follow-up at 18 months corrected gestational age.

Intervention Type
Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)
Neonatal parenteral nutrition formulation

Primary outcome(s)
To compare early head growth in premature infants receiving a standardised formulation of parenteral nutrition(scNPN) with a standardised, concentrated formulation of parenteral nutrition containing additional protein, fat and carbohydrate (scNPNmax). Timepoints: when the infant is 28 days old (having already had growth measurements on days 0, 7, 14 and 21).

Key secondary outcome(s))
1. Weight gain and linear growth
2. Monitoring supplementary infusion requirements such as insulin and electrolytes
3. Routine biochemical measures of PN tolerance
4. Cost-benefit analysis
5. Efficiency and safety of prescribing and administration
6. Neurodevelopmental outcome (Bayley III)

Timepoints:
For outcomes 1 - 5: At 28 days and 36 weeks post conceptual age
For outcome 6: At 18 months corrected for gestational age

Completion date
01/05/2013

Eligibility

Key inclusion criteria
All infants (both males ane females) born less than 29 weeks gestation and weighing <1,200 grams born at Liverpool Women's Hospital (LWH) will be eligible. All infants meeting these criteria born outside LWH will be eligible if transfer takes place to LWH within 48 hours.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Infants born in poor condition in the first 72 hours and are unlikely to survive the first week after birth
2. Infants diagnosed with major congenital and chromosomal abnormalities know to affect head growth or gastrointestinal function

Date of first enrolment
01/06/2009

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lead Research Nurse
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Liverpool Women's Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/04q5r0746

Funder(s)

Funder type
Charity

Funder Name
BLISS (UK) - Innovations in Care Programme

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?
Results article	results	01/06/2013		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	01/05/2015		Yes	No
Results article		10/11/2023	27/11/2023	Yes	No
Protocol article	protocol	10/06/2011		Yes	No
HRA research summary			28/06/2023	No	No