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Extreme Preterm Nutrition Study

Submission date 08/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/02/2006	**Overall study status** Completed	
Last Edited 26/10/2022	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LWH0502

Study information

Scientific Title
Extreme Preterm Nutrition Study

Acronym
ExPN study

Study objectives
Will better nutrition improve head growth and neurodevelopmental outcome in very preterm infants?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Liverpool Children's Research Ethics Committee on 29th September 2003 (ref: 03/08/141/C).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Extreme prematurity

Interventions
Hyperalimentation - providing 20% more calories in total parenteral nutrition followed by 20% more protein in enteral feeds, from birth to 34 weeks corrected gestational age
Control: usual care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Head circumference at 36 weeks corrected gestational age

Secondary outcome measures
1. Quantitative cranial Magnetic Resonance Imaging (MRI) analysis at 40 weeks corrected gestational age
2. Neurodevelopmental assessment using Bayley's Scales of Infant Development II (BSID-II) at three months and nine months post-term

Overall study start date
26/01/2004

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Babies (singletons/twins) born less than 29 completed weeks gestation, but at least 24 weeks gestation and above

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
140

Key exclusion criteria
Babies born with major congenital malformations, triplets and other higher multiple births

Date of first enrolment
26/01/2004

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Neonatal Unit
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Liverpool Women's NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04q5r0746

Funder(s)

Funder type
Government

Funder Name
'Own account', fully funded by Liverpool Women's NHS R&D support funds (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/09/2008		Yes	No
Results article		01/09/2008		Yes	No