

Extreme Preterm Nutrition Study

Submission date 08/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/10/2022	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Head circumference at 36 weeks corrected gestational age

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

Study participating centre

Neonatal Unit

Liverpool

United Kingdom

L8 7SS

Sponsor information

Organisation

Liverpool Women's NHS Foundation Trust (UK)

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

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?
Results article		01/09/2008		Yes	No
Other publications		01/09/2008		Yes	No