

Extreme Preterm Nutrition Study

Submission date 08/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Richard Cooke

Contact details
Neonatal Unit
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS
+44 (0)151 708 9988
mc19@liv.ac.uk

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

Crown Street
Liverpool
England
United Kingdom
L8 7SS
+44 (0)151 708 9988
lynne.webster@lwh.nhs.uk

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