# **Extreme Preterm Nutrition Study**

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

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

**Prof Richard Cooke** 

#### Contact details

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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