Speed of increasing milk feeds

Summary Protocol

Introduction

Very preterm babies are unable to tolerate nutritional volumes of milk without complications so require parenteral nutrition whilst milk feeds are built up. The best rate of increasing these feeds to achieve full milk feeds without causing complications is not yet known and a trial is needed to determine this balance. Short and long-term outcomes for preterm babies are affected by strategies that reduce infection rates, reduce necrotising enterocolitis rates, promote adequate growth, and encourage earlier discharge. Feeding strategies impact on all of these and this study will examine two rates of increasing milk feeds with a primary focus of determining the effect on rate of survival without moderate or severe disability. The trial will recruit 2,800 infants from approximately 30 neonatal units within the UK and Ireland over 3 years commencing in early 2013.

Eligibility:

Inclusion criteria:

- Gestational age at birth <32 weeks, or birth weight <1,500 g
- The infant is receiving ≤30 ml/kg/day of milk at randomisation
- Written informed parental consent is obtained

To ensure the widest applicability to preterm infants across the UK, those exclusively breast milk fed, formula milk fed, or receiving mixed feeds will be included

Exclusion criteria:

- Infants with severe congenital anomalies
- Infants who, in the opinion of the treating clinician, have no realistic chance of survival
- Infants who are unlikely to be traceable for follow-up at 24 months of age (for example, infants of non-UK residents)

Recruitment and randomisation:

Informed written consent will be obtained from parents after a full verbal and written explanation of the study. The responsible clinicians will meet with the parents during the intervention period to ensure that they have understood the trial procedures and continue to consent to participate in the trial. Randomisation is via a secure website at the NPEU Clinical Trials Unit in Oxford. A telephone backup system will be available 24 hours a day.

The interventions:

Infants will be randomly allocated to receive either a fast (30 ml/kg/day) or slow (18 ml/kg/day) increase in milk feed volumes.

Primary outcome:

The primary outcome will be the proportion of infants surviving without moderate or severe developmental disability at 24 months of age corrected for prematurity. This will be collected using a validated parent questionnaire.

Secondary outcomes:

- Microbiologically-confirmed or clinically suspected late-onset infection from trial entry until hospital discharge
- Necrotising enterocolitis (Bells stage 2 or 3) from trial entry until hospital discharge
- Time taken to reach full milk feeds (tolerating 150 ml/kg/day for 3 consecutive days)
- Growth (weight and head circumference) at discharge
- Duration of parenteral feeding before discharge
- Length of time in intensive care
- Length of hospital stay
- Diagnosis of cerebral palsy by doctor or other health professional (parent reported)

Statistical analysis:

Comparative analyses will be restricted to babies who are assigned to the two groups. Specifically, babies will be analysed in the groups to which they are assigned.

Contact Details:

Chief Investigator

Dr Jon Dorling

Neonatal Unit
Queens Medical Centre
Derby Road
Nottingham
NG7 2UH

SIFT Trial Coordinator

NPEU Clinical Trials Unit
National Perinatal Epidemiology Unit
University of Oxford, Old Road Campus
Oxford, OX3 7LF

T: 01865 617 919

F: 01865 289 740

E: sift@npeu.ox.ac.uk

W: www.npeu.ox.ac.uk/sift

UNIVERSITY OF OXFORD

NHS National Institute for Health Research

npeu National Perinatal Epidemiology Unit