THE DIAMOND TRIAL

DIfferent Approaches to MOderate & late preterm Nutrition: Determinants of feed tolerance, body composition and development

Tanith Alexander,[1,2] Dr Michael Meyer,[1,3] Dr Jane Alsweiler,[3,6] Prof Jane Harding,[2] Dr Yannan Jiang,[5] Dr Clare Wall,[4] and Prof Frank Bloomfield[2,6]

Background

- Babies born moderate--late preterm (32^{+0} – 36^{+6} weeks' gestation) account for >80% of all preterm births.
- Despite excellent survival, these babies remain at risk of adverse neurodevelopmental outcomes, cardiovascular disease, obesity and diabetes.

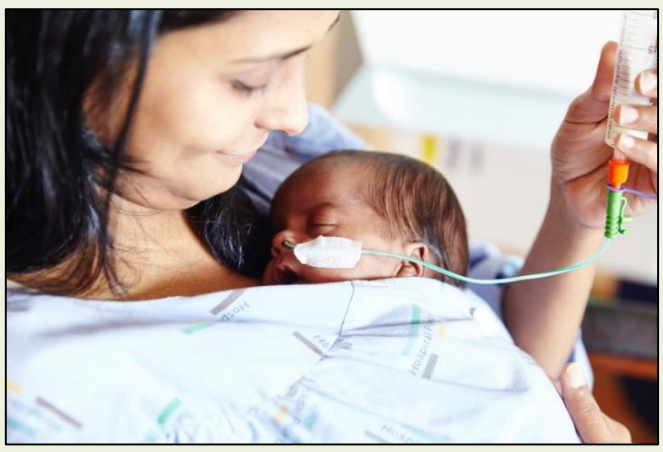
Aim

To investigate the impact of different feeding strategies currently used in NZ to support nutrition of moderate–late preterm babies whilst full enteral feeds with breast-milk are established on:

- Body composition
- Feed tolerance
- Microbiome composition and activity
- Neurodevelopmental outcome

Inclusion criteria

- Born between 32^{+0} and 35^{+6} weeks' gestation
- Mother intends to breast-feed
- Admitted to the Neonatal Care Unit
- Requires insertion of intravenous line for clinical reasons



Method

- Multi-site, randomised, factorial trial.
- Sample size: 528 babies
- Intervention: One of 8 conditions for nutritional support before full enteral feeds with breast-milk are established:

  (i) Parenteral nutritional: an amino acid solution P100 (+), or 10% dextrose (-)

  (ii) Enteral nutrition: human milk substitute complementary feeds (+) or no complementary feeds exclusive breast-milk (-)

  (iii) Sensory stimulus before feeds: taste/smell of milk (+), or no taste/smell or milk prior to feeds (-)

Condition	Parenteral nutrition (i)	Milk supplement (ii)	Taste/smell (iii)
1	+	+	+
2	+	-	+
3	+	+	-
4	+	-	-
5	-	+	+
6	-	-	+
7	-	+	-
8	-	-	-

Table 1: Factorial design trial

+, baby receives this intervention;
-, baby does not receive this intervention.

Outcomes

Primary outcomes:

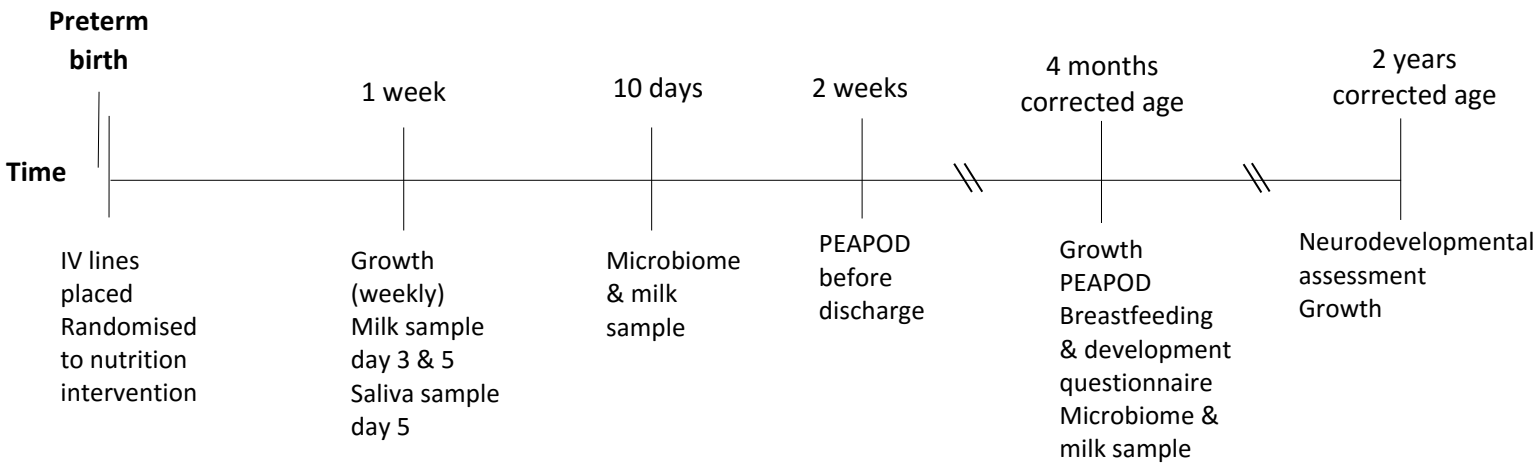
- % fat mass at 4 months' corrected age measured by air displacement plethysmography (PEAPOD) (for parenteral and enteral nutrition support interventions (i) and (ii))
- Time to full enteral feeds (for smell/taste before feeds (iii))

Secondary outcomes:

- Length of hospital stay
- Time to full sucking feeds
- Neurodevelopmental assessment
- Fully breast-fed rates at 4 months
- Gut microbial composition and activity
- Maternal milk composition

PEAPOD: standard method for infant body composition assessment

Figure 1: Flow chart of the DIAMOND study from birth to 2 years' corrected age



Relevance

This trial will provide the first evidence from a randomised clinical trial on how common nutritional support strategies in moderate- to late-preterm infants impact upon metabolic and developmental outcomes.

The trial will enable the development of a package of care that will optimise long-term outcomes and the development of nutrition care guidelines.

1. Neonatal Unit, Kidz First, Middlemore Hospital, Auckland, New Zealand
2. Liggins Institute, The University of Auckland
3. The Department of Paediatrics: Child and Youth Health, The University of Auckland
4. Department of Nutrition, Faculty of Medical and Health Sciences, The University of Auckland
5. Dept of Statistics, Faculty of Science, The University of Auckland, New Zealand
6. Newborn Services, Auckland City Hospital, Auckland, New Zealand