



# Pediatric Academic Societies Meeting

April 24 – May 1, 2019 | Baltimore, MD

April 24-26 • Pre-conference Events | April 27-30 • PAS 2019 Meeting | May 1 • Post-conference Events

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Optimizing Individual Nutrition in Preterm Infants: Randomized Clinical Trial (RCT)

Mon,  
April 29

Convention  
Center  
341-342

Platform

Part of:

**3685 Neonatal Fetal Nutrition & Metabolism II**

3:30 PM - 5:30 PM

Info

## Background:

In preterm infants fed human milk, milk fortification can be adjusted by (1) optimization, based on growth rate and serum analyses) or 2) individualization, based on daily human milk nutrient analysis.

## Objective:

The 1st specific aim was to determine whether individualized and optimized nutrition in the neonatal intensive care unit (NICU) results in improved growth to 36 weeks (wks) postmenstrual age or discharge in neonates <29wks gestational age (GA) and in small for GA (SGA, birthweight<10th percentile for GA) neonates <34wks compared with optimized nutrition (controls). The 2nd specific aim was to determine whether individualized and optimized nutrition in the NICU reduces the risk of disproportionate growth (body mass index [BMI]>90th centile) in

the NICU.

**Design/Methods:**

This double-blinded parallel group RCT was registered at ClinicalTrials.gov **NCT02372136**. Randomization was done using random block allocation and stratification by GA and size for age (AGA/LGA 23-28wks, SGA 23-28wks and SGA 29-34wks). In controls, milk fortification was optimized weekly by the clinical team based on serum analyses, weight gain and linear growth. In the experimental group breast milk macronutrients were adjusted daily by formula technicians based on measurements using near-infrared spectroscopy, aiming at concentrations similar to averages in donor milk; these adjustments were blinded to clinical and study teams. In addition, milk fortification was optimized weekly as in controls. A sample size of 100 was needed for the 1st specific aim. A Data Safety Monitoring Committee reviewed predetermined adverse events (death, necrotizing enterocolitis, feeding intolerance, sepsis) every 6 months. This study was funded by the Children's Foundation (LPB), the Gerber Foundation (LPB) and George L. MacGregor Professorship (CRR).

**Results:**

Baseline data were similar in both groups (Table 1). Among 120 randomized neonates, both primary outcomes were available in 104 (Figure 1). Experimental and control groups had similar average weight gain ( $13.0 \pm 2.6$  vs.  $13.1 \pm 2.1$  g·kg<sup>-1</sup>·day<sup>-1</sup>,  $P=0.37$ ), linear growth ( $0.9 \pm 0.2$  vs.  $0.9 \pm 0.2$  cm·week<sup>-1</sup>,  $P=0.90$ ) and frequency of weight/length disproportion (2% vs. 2%,  $P=1.00$ ) at 36wks or discharge (Table 2). Adverse events were similar in the 2 groups (Table 3).

**Conclusion(s):**

In this RCT, adjusting macronutrients based on breast milk analysis in PT neonates did not improve weight gain, linear growth or weight/length disproportion. Follow-up to 3 years of age and analysis of serial milk samples and supplementation are underway.

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3685.5

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