

Title of Abstract:

Short Term Outcomes in Infants Enrolled vs. Eligible but Not Enrolled in an RCT

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Abstract Description:

Background: A multicenter RCT to evaluate the effect of patterned, frequency-modulated, somatosensory stimulation on time to full oral feeds (FOF) and length of stay (LOS) was concluded in 2015 and the results were previously presented. Emerging evidence highlights the importance of examining outcomes in eligible infants who are not enrolled.^{1, 2} If the eligible but not enrolled infants are different than those enrolled in study, it may limit the generalizability of the study findings.

Objective: To compare the study and NICU outcomes in infants enrolled to those eligible but not enrolled, during a multicenter RCT, from a single study site.

Methods: This is a retrospective analysis of preterm infants born between 26 and 30 weeks of gestational age (GA), from Jan 2011 to Dec 2015 at a single center. We compared the demographics, study outcomes, and neonatal outcomes of infants enrolled in study to those eligible but not enrolled using Wilcoxon rank-sum test, Chi square or Fisher's exact test as appropriate.

Results: Of the 130 eligible infants, 68% were enrolled in the study. Infants enrolled in the study were smaller, less mature, had longer LOS and reached FOF later (Table 1). However, after adjusting for GA, there was no difference in the time to reach FOF or LOS which were the primary and secondary outcomes respectively. Similarly, there was no difference in death or other neonatal outcomes between the two groups.

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Conclusion: Infants eligible, but not enrolled in the RCT are no different from those enrolled in the study. This reflects non-divergent outcomes and is reassuring that those enrolled in the study are representative of the population being studied.

References:

1. Foglia EE, Nolen TL, DeMauro SB et al. Research Letter: Short-term Outcomes of Infants Enrolled in Randomized Clinical Trials vs Those Eligible but Not Enrolled. JAMA June 15, 2016, Volume 313, Number 23, 2327-29
2. Rich W, Finer NN, Gantz MG et al. Enrollment of Extremely Low Birth Weight Infants in a Clinical Study may not be Representative. Pediatrics 2012; 129:480-484.

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