

A Nutrient Formulation Affects Brain Myelination in Infants: An Investigative Randomized Controlled Trial

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Abstract : Observational neuroimaging studies suggest differences between breast-fed and formula-fed infants in developmental myelination, a key brain process for learning and cognitive development. However, the possible effects of a nutrient formulation on myelin development in healthy term infants in an intervention study have not been investigated. Objective was, therefore, to investigate the efficacy of a nutrient formulation with higher levels of myelin-relevant nutrients as compared to a control formulation with lower levels of the same nutrients on brain myelination and cognitive development in the first 6 months of life. The study is an ongoing randomized, controlled, double-blind, two-center, parallel-group clinical trial with a nonrandomized, non-blinded arm of exclusively breastfed infants. The current findings result from a staged statistical analysis at 6 months; the recruitment and intervention period has been completed for all participants. Follow-up visits at 12, 18 and 24 months are still ongoing. N= 81 enrolled full term, neurotypical infants of both sexes were randomized into either the investigational (N= 42) or the control group (N= 39), and N= 108 children in the breast-fed arm served as a natural reference group. The effect of a blend of docosahexaenoic acid, arachidonic acid, iron, vitamin B12, folic acid as well as sphingomyelin from a uniquely processed whey protein concentrate enriched in alpha-lactalbumin and phospholipids in an infant nutrition product matrix was investigated. The main outcomes for the staged statistical analyses at 6 months included brain myelination measures derived from MRI. Additional outcomes were brain volume, cognitive development and safety. The full analyses set at 6 months comprised N= 66 infants. Higher levels of myelin-relevant nutrients compared to lower levels resulted in significant differences in myelin structure, volume, and rate of myelination as early as 3 and 6 months of life. The cross-sectional change of means between groups for whole-brain myelin volume was 8.4% for investigational versus control formulation (3.5% versus the breastfeeding reference) group at 3 months and increased to 36.4% for investigational versus control formulation (14.1% versus breastfeeding reference) at 6 months. No statistically significant differences were detected for early cognition scores. Safety findings were largely similar across groups. This is the first pediatric nutritional neuroimaging study demonstrating the efficacy of a myelin nutrient blend on developmental myelination in well-nourished term infants. Myelination is a critical process in learning and development. The effects were demonstrated across the brain, particularly in temporal and parietal regions, known to be functionally involved in sensory, motor and language skills. These first results add to the field of nutritional neuroscience by demonstrating early life nutrition benefits for brain architecture which may be foundational for later cognitive and behavioral outcomes. ClinicalTrials.gov Identifier: NCT03111927 (Infant Nutrition and Brain Development - Full-Text View - ClinicalTrials.gov).

Keywords : brain development, infant nutrition, MRI, myelination

Conference Title : ICMICN 2021 : International Conference on Maternal, Infant and Child Nutrition

Conference Location : Tokyo, Japan

Conference Dates : December 02-03, 2021