

Gastrointestinal (GI) tolerance and hydration status of newborn infants fed soy-based infant formulas with supplemental fructooligosaccharides (FOS). J. Lasekan, S. Acosta, D. Albrecht, G. Baggs, Abbott Nutrition, Abbott Laboratories, Columbus, OH, USA

GI benefits of oligosaccharides have been clinically documented for human milk and milk-based formulas in infants, but not for soy-based formulas. Thus, GI tolerance and safety of 2 experimental soy formulas with supplemental FOS were assessed at 14 and 35 d of age in 0-8 d old healthy term infants in a randomized, double-blind, parallel prospective trial vs a commercial soy formula (Isomil Advance with sucrose as 20% of total carbohydrate; CF, n=62 infants) with history of safe use. The 2nd formula (EF1, n=64) was similar to CF but contained supplemental FOS (2.5g/L) and carotenoids (lutein, lycopene, β -carotene); and the 3rd formula (EF2, n=62) was similar to EF1 but contained maltodextrin instead of sucrose. Study completion rates were CF=81, EF1=86, & EF2=87%. No differences ($p > 0.05$) were noted in mean rank stool consistency (primary variable), stool frequency, formula intake, spit-up/vomit, growth (weight, length, head circumference), and safety measures (urine specific gravity, hydration status and serious adverse events). Urine specific gravities for the 3 groups were normal (< 1.03). EF1 had higher % yellow stools vs CF ($p < 0.014$ at age 0-14 d). The study suggested that soy-based infant formulas supplemented with 2.5g FOS/L, and carotenoids, with or without sucrose, are safe and well tolerated by term newborn infants.