

Schmelzle *et al.*, Randomized double-blind study of the nutritional efficacy and bifidogenicity of a new infant formula containing partially hydrolyzed protein, a high beta-palmitic acid level, and nondigestible oligosaccharides. *J Pediatr Gastroenterol Nutr*, 2003; 36(3):343-51.

Abstract

Objectives: The aim of this study was to evaluate the nutritional efficacy and bifidogenic characteristics of a new infant formula containing partially hydrolyzed whey protein, modified vegetable oil with a high beta-palmitic acid content, prebiotic oligosaccharides, and starch.

Methods: In a double-blind study, healthy formula-fed term infants aged younger than 2 weeks were randomized to receive either the new infant formula (NF) or a standard formula (SF) until the age of 12 weeks. Anthropometric measurements were taken at enrollment, 6 weeks, and 12 weeks. In a subsample of infants, blood samples were taken at 6 weeks and stool samples were taken at enrollment and 6 weeks. Blood samples were analyzed for biochemical measures of protein status and amino acids, and stools were analyzed for total bacteria and bifidobacteria. Mothers completed a feeding diary and questionnaire at 6 and 10 weeks.

Results: One hundred fifty-four infants were enrolled in the study; 102 completed the trial. The growth of infants in both formula groups was in line with published growth curves. During the first 6 weeks, NF girls gained more weight and head circumference than the SF girls. These velocity differences were not maintained throughout the 12-week study period. The NF stools had a higher proportion of bifidobacteria at 6 weeks compared with the SF stools, and they were softer. There were no clinically significant differences in the blood biochemical and amino acid values between groups. Both formulas were well tolerated by the infants.

Conclusions: When compared with a standard infant formula, the new formula supported satisfactory growth, led to higher counts of bifidobacteria in the feces, produced blood bio-chemical values typical of formula-fed infants, and was well tolerated.