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Milk fat-based formula reduced palmitic acid soaps and excretion of calcium in healthy term infants: two double-blind, randomized, cross-over trials

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Abstract

Introduction: Infant formula (IF) with vegetable fat blends typically have more than 80% of palmitic acid (PA) esterified at the *sn*-1 and *sn*-3 positions of triglycerides. Additional use of bovine milk fat (MF), a natural source of *sn*-2 palmitate, may enable increasing the *sn*-2 palmitate levels, potentially leading to improved absorption of fatty acids and calcium, and reduced formation of PA soaps associated with constipation in infants. The current study investigated the effect of IF with and without MF on the concentration of PA, PA soaps, calcium excretion and gastrointestinal tolerance using Amsterdam Infant Stool Scale (AISS) in healthy term infants.

Materials and Methods: Two double-blind randomized placebo-controlled cross-over trials were conducted in parallel to compare a MF-based test formula with high *sn*-2 palmitate levels (39%) with a reference formula with only vegetable fat (10.1% *sn*-2 palmitate, cross-over study 1; CS1) and a MF-based test formula with medium *sn*-2 palmitate levels (19.7%) with the reference formula with only vegetable fat (cross-over study 2; CS2). CS1 included 17 and CS2 18 full-term, healthy, exclusively formula-fed infants screened between the 9^{th}-14^{th} week of age. After two weeks of wash-out period, in both CS1 and CS2, infants were randomized to receive either the MF-based test formula or reference. At the end of two weeks, the groups were crossed-over to receive the other formula for subsequent two weeks. Stool samples were collected after each two-week intervention period and bi-weekly diaries and questionnaires were completed by the parents/caretakers.

Results: The PA concentrations in stools (mg/g dry weight) did not differ between the MF-based test and reference formula in either CS1 ($p = 0.1324$) or CS2 ($p = 0.1198$). A reduction was observed in the concentration of PA soaps in both medium and high *sn*-2 palmitate formula, with a more pronounced effect for the high *sn*-2 palmitate formula (medium; $p = 0.0023$ and high; $p < 0.0001$). In addition, calcium excretion in stools was significantly lower in the MF-based formula groups as compared to the reference in both studies (medium; $p = 0.0067$ and high; $p = 0.0041$). In CS2, stool consistency did not differ between groups whilst in CS1, a favorable effect of high *sn*-2 palmitate formula compared to the reference formula ($p = 0.0008$) was noted.

Conclusion: Bovine milk fat in infant formula reduced the excretion of PA soaps and calcium in stool samples of healthy term infants. High *sn*-2 palmitate formula showed a more pronounced effect and improved stool consistency according to the AISS.

Conflict of Interest

There is no real or perceived conflict of interest. Inge Thijs-Verhoeven, Marlotte Vonk, Rolf Bos and Panam Parikh are employees of FrieslandCampina.