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Long-term safety and impact on infection rates of postnatal probiotic and prebiotic (synbiotic) treatment: randomized, double-blind, placebo-controlled trial.

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Source

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Abstract

OBJECTIVE:
Live probiotic bacteria and dietary prebiotic oligosaccharides (together termed synbiotics) increasingly are being used in infancy, but evidence of long-term safety is lacking. In a randomized, placebo-controlled, double-blind trial, we studied the safety and long-term effects of feeding synbiotics to newborn infants.

METHODS:
Between November 2000 and March 2003, pregnant mothers carrying infants at high risk for allergy were randomly assigned to receive a mixture of 4 probiotic species (Lactobacillus rhamnosus GG and LC705, Bifidobacterium breve Bb99, and Propionibacterium freudenreichii ssp shermanii) or a placebo for 4 weeks before delivery. Their infants received the same probiotics with 0.8 g of galactooligosaccharides, or a placebo, daily for 6 months after birth. Safety data were obtained from clinical examinations and interviews at follow-up visits at ages 3, 6, and 24 months and from questionnaires at ages 3, 6, 12, and 24 months. Growth data were collected at each time point.

RESULTS:
Of the 1018 eligible infants, 925 completed the 2-year follow-up assessment. Infants in both groups grew normally. We observed no difference in neonatal morbidity, feeding-related behaviors (such as infantile colic), or serious adverse events between the study groups. During the 6-month intervention, antibiotics were prescribed less often in the synbiotic group than in the placebo group (23% vs 28%). Throughout the follow-up period, respiratory infections occurred less frequently in the synbiotic group (geometric mean: 3.7 vs 4.2 infections).

CONCLUSION:
Feeding synbiotics to newborn infants was safe and seemed to increase resistance to respiratory infections during the first 2 years of life.

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