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Oral supplementation with probiotics in very-low-birth-weight preterm infants: a randomized, double-blind, placebo-controlled trial.

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Source

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Abstract

BACKGROUND:
Although recent reports suggest that supplementation with probiotics may enhance intestinal function in premature infants, the mechanisms are unclear, and questions remain regarding the safety and efficacy of probiotics in extremely low-birth-weight infants.
OBJECTIVE:
The objective was to evaluate the efficacy of probiotics on the digestive tolerance to enteral feeding in preterm infants born with a very low or extremely low birth weight.
DESIGN:
In a bicentric, double-blind, randomized controlled clinical trial that was stratified for center and birth weight, 45 infants received enteral probiotics (Bifidobacterium longum BB536 and Lactobacillus rhamnosus GG; BB536-LGG) and 49 received placebo. The primary endpoint was the percentage of infants receiving >50% of their nutritional needs via enteral feeding on the 14th day of life. A triangular test was used to perform sequential analysis.
RESULTS:
The trial was discontinued after the fourth sequential analysis concluded a lack of effect. The primary endpoint was not significantly different between the probiotic (57.8%) and placebo (57.1%) groups (P = 0.95). However, in infants who weighed >1000 g, probioticsupplementation was associated with a shortening in the time to reach full enteral feeding (P = 0.04). Other than colonization by the probioticstrains, no alteration in the composition of intestinal microbiota or changes in the fecal excretion of calprotectin was observed. No colonization by probiotic strains was detected in infants who weighed < or =1000 g, presumably because of more frequent suspensions of enteral feeding, more courses of antibiotic treatment, or both.
CONCLUSIONS:
Supplementation with BB536-LGG may not improve the gastrointestinal tolerance to enteral feeding in very-low-birth-weight infants but may improve gastrointestinal tolerance in infants weighing >1000 g. This trial was registered at clinicaltrials.gov as NCT 00290576.

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