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**FILE: ■Probiotics
■Pediatrics
■Necrotizing Enterocolitis**

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RE: Study Shows Reduction in Necrotizing Enterocolitis in Infants

Lin HC, Su BH, Chen AC, Lin TW, Tsai CH, Yeh TF, Oh W. Oral probiotics reduce the incidence and severity of necrotizing enterocolitis in very low birth weight infants. *Pediatrics*. January 2005;115(1):1-4.

Necrotizing enterocolitis (NEC), a serious gastrointestinal disease, is a worldwide problem in very low birth weight (VLBW) infants. Mortality rates from NEC have declined due to improved supportive and surgical care, but effective preventive strategies are lacking. *Lactobacillus acidophilus* and *Bifidobacterium infantis* have been used as probiotics—nonpathogenic bacteria that colonize the intestine to benefit the patient—to reduce the incidence of NEC. However, the dosage, duration, safety, and efficacy of probiotics are controversial. The purpose of this study was to evaluate Infloran®, an oral probiotic, to see if it could reduce the incidence and severity of NEC in VLBW infants.

This prospective, double-blind, randomized, controlled study was conducted in the neonatal intensive care unit of China Medical University Hospital in Taiwan. Infants with a birth weight less than 3.3 pounds (1500 grams) who started to feed orally and were at least 7 days old participated. Patients ($n = 367$) received breast milk or breast milk plus 125 mg/kg Infloran (*L. acidophilus* and *B. infantis*; Berna Biotech Ltd, Berne, Switzerland) twice daily until discharge. A strict feeding protocol was followed for all participants. The diagnosis and classification of NEC was made by 2 independent senior attending neonatologists.

The maternal and infant clinical and demographic characteristics did not differ between the groups. The incidence of death or NEC was significantly lower in the probiotics group as compared to the control group ($P = 0.009$). The probiotics group also had a significantly lower incidence of severe NEC ($P = 0.03$) and sepsis (infection of bacteria in the blood) ($P = 0.03$).

The authors conclude that Infloran can reduce the incidence and severity of NEC in VLBW infants. Probiotics may protect high-risk infants by competitively excluding pathogenic bacteria, modifying the patient's response to microbial products, and enhancing oral nutrition, which inhibits growth of pathogens. Unfortunately the trial was not sufficiently powered statistically to evaluate safety with regard to the possible risk for *Lactobacillus* or *Bifidobacterium* sepsis. Additional safety studies are needed.

—*Heather S. Oliff, PhD*

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