

**TITLE: SAFETY TRIAL OF AN INFANT FORMULA ENRICHED WITH THE HUMAN MILK  
PROBIOTIC STRAIN *L.fermentum* CECT5716.**

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**INTRODUCTION:** Breast milk of healthy mother contains lactic acid bacteria with probiotic potential which could be responsible of the some of the beneficial effect of the breast milk. *Lactobacillus fermentum* CECT5716, a probiotic strain originally isolated from breast milk, has shown beneficial effect on health of adults and infants in previous studies.

**OBJECTIVE:** To evaluate the safety and tolerance of the consumption of an initial infant formula supplemented with *L.fermentum* CECT5716 in neonates from 1 to 6 months of life.

**METHODS:** A randomized double blinded controlled study including 126 infants at the age of 1 month was conducted. Infants were assigned randomly to either infant formula supplemented with *L.fermentum* (Probiotic group), or the same formula without the probiotic strain (Control group). The primary outcome of the study was the average daily weight gain between baseline (1 month of life) and 6 months. Secondary outcomes for safety were other anthropometric data (length and head circumference) and formula consumption and tolerance. Incidence of infections was also recorded by pediatricians.

**RESULTS:** No differences in weight gain were observed between groups (25.3±6.0 vs 24.8±5.1 g/day). The growth of the infants of both groups was similar. There were no statistically significant differences in the consumption of formula by infants of both groups. Regarding to symptoms related with the tolerance of the formula there were no significant differences between control and probiotic group in the incidence of infantile colic, spitting up or constipation. Finally the incidence rate of diarrhoea in infants of control group was 3 times higher than in the probiotic group (p=0.02). No significant differences were observed in the rate of incidence of respiratory infections.

**CONCLUSION:** The consumption from 1 to 6 months of life of an infant formula enriched with the human milk probiotic strain *L.fermentum* CECT5716 is well tolerated and safe.

**KEYWORDS:** Probiotics, infant formula, neonates, safety, infections.