

Savino *et al.*, Reduction of crying episodes owing to infantile colic: a randomized controlled study on the efficacy of a new infant formula. *EJCN*, 2006; doi:10.1038/sj.ejcn.1602457

#### Abstract

**Objectives:** The aim of this study was to evaluate the efficacy on crying episodes owing to infantile colic of a new infant formula containing partially hydrolysed whey proteins, prebiotic oligosaccharides (OS), with a high  $\beta$ -palmitic acid content. **Design:** Prospective randomized controlled study. **Setting:** Italy. **Subjects:** Two hundred and sixty-seven formula-fed infants, aged less than 4 months, with infantile colic, were randomized to receive either the new infant formula (study treatment (ST)) or a standard formula and simethicone (6 mg/kg twice a day) (control treatment (CT)). A questionnaire was given to parents to evaluate for 14 days the daily number of colic episodes and crying time. **Results:** Out of the 199 infants who completed the study, 96 were treated with the new formula and 103 were not treated. Infants receiving the new formula had a significant decrease in colic episodes after 1 week ( $2.47 \pm 1.94$  at day 7 vs  $5.99 \pm 1.84$  at the study entry) compared to infants receiving the CT ( $3.72 \pm 1.98$  at day 7 vs  $5.41 \pm 1.88$  at the study entry) ( $P < 0.0001$ ). Also at day 14, the crying episodes were significantly different between the two groups of infants ( $1.76 \pm 1.60$  in ST vs  $3.32 \pm 2.06$  in CT) ( $P < 0.0001$ ). **Conclusions:** The use of a partially hydrolysed formula supplemented with fructo- and galacto-OS induces a reduction of crying episodes in infants with colic after 7 and 14 days when compared with a standard formula and simethicone.