

Presented at the 17th International Congress of Nutrition, Vienna, Austria, August 2001:

Randomized controlled trial of microencapsulated ferrous fumarate 'sprinkles' and ferrous sulfate drops, for treatment and prevention of anemia in Ghanaian infants

S Zlotkin, P Arthur, K Y Antwi, G Yeung. Depts of Paediatr and Nutr Sci, University of Toronto, Div of Gastroent & Nutr, Hospital for Sick Children, Toronto, Canada and Kintampo Health Res. Centre, Ghana.

Background: The standard treatment of anemia in infants is ferrous sulfate (DROPS) given 3-times daily. Adherence to long-term use of DROPS is often poor. Thus we developed a novel delivery system with microencapsulated ferrous fumarate and ascorbic acid (SPRINKLES) that can be sprinkled onto complementary foods.

Aim. To compare the use of SPRINKLES (\pm vitamin A) vs DROPS in the treatment and prevention of anemia in infants. **Methods.** A randomized controlled trial in 2 consecutive phases: (i) Treatment Phase: 557 anemic children (age 6-18 mo; hemoglobin (Hb) 70-99 g/L) in rural Ghana were studied. One group received daily SPRINKLES (80 mg Fe); and the control group DROPS 3-times daily (40 mg Fe, total) for 2 months. In both studies, Hb and serum ferritin (ferr) values were measured at baseline and end. (ii) Prevention Phase: Infants who recovered from anemia in the initial phase of the study were eligible. 324 children (age 15.6 ± 4.5 mo; Hb > 100g/L, ferr > 12mg/L) were studied for 6 months with daily intervention. Four groups included: (1) DROPS, 12.5 mg Fe; (2) PLACEBO, no Fe; (3) SPRINKLES, 40 mg Fe; and (4) SPRINKLES with vitamin A, 40 mg Fe + 2000 IU RE. **Results.** (i) Successful treatment of anemia (Hb > 100g/L) occurred in 58% of SPRINKLES group, and in 56% of the DROPS group ($p=0.51$). Ferr levels increased in each group from baseline to end ($p=0.001$). (ii) Among the 4 groups, there were no significant differences in mean Hb values (112.2 ± 14.7 g/L, $p=0.70$) or ferr (median = 62.8mg/L) from baseline to end. During the trial, 82.4% maintained their non-anemic status. **Conclusions.** Use of DROPS or SPRINKLES resulted in a similar rate of successful treatment of anemia. In previously treated infants, there is no need for further intervention to prevent anemia at least for 6 months. Sprinkles were well accepted without side effects in both phases. **Implications.** Although beyond the scope of this study, improved adherence and ease of use may favor the use of SPRINKLES to deliver iron for intervention programs in developing countries. Supported by USAID's OMNI Research Program through the HNI of ILSI.