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Part 2. Randomized prospective placebo-controlled trial of microencapsulated ferrous fumarate 'sprinkles' with and without vitamin a and ferrous sulfate drops, for prevention of anemia in infants

Background: Successful treatment of anemia may not reverse its negative developmental sequelae in children; thus, primary prevention should be the goal of intervention programs. Long-term prophylactic use of ferrous sulfate drops (DROPS) is not effective due to poor compliance, thus alternatives must be found. Previously, we demonstrated that DROPS or microencapsulated ferrous fumarate sprinkles (SPRINKLES) were both efficacious in treating 60% of children with anemia. Among the possible causes for the lack of response (in 40%) was vitamin A deficiency since 48% were deficient. Thus our **AIM** was to compare the use of SPRINKLES (with and without vitamin A) to DROPS for the prevention of anemia. **Methods:** We studied 324 Ghanaian children (mean age 15.64 ± 4.47 months; hemoglobin (Hb) >100 g/L) for 6 months using a prospective randomized placebo-controlled design. These previously anemic infants had received treatment with iron for 2 months prior to enrollment. Four groups included: (1) DROPS; (2) placebo sachet; (3) SPRINKLES; and (4) SPRINKLES with vitamin A. Hb and ferritin (FERR) values were measured at baseline and end. **Results:** 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=62.8 range=0.0-363.6mg/L) from baseline to the end. During the trial, 82.4% maintained their non-anemic status. Sprinkles were well accepted without complications. **Conclusions:** In previously treated infants, there is no need for further intervention to prevent anemia at least for 6 months. These results have important implications for iron intervention programs in developing countries where initial treatment may be necessary because of a high prevalence of anemia. Supported by USAID's OMNI Research Program through the HNI of ILSI. Material support from Mead Johnson Canada & Nestle Canada.