## Abstract of the study

**Objectives and study:** Iron deficiency (ID) and vitamin D deficiency (VDD) are common among young European children because of low dietary intakes. Studies to evaluate the effect of milk fortification on iron and vitamin D status of young European children are scarce. We therefore investigated the effect of a micronutrient-fortified young child formula (YCF) on the iron and vitamin D status of healthy 12-36 months old children living in Western-Europe.

**Methods:** This randomised, double-blind controlled trial was performed in Germany, the Netherlands, and the United Kingdom in 2012-2014. A total of 318 children received either YCF (1.2mg/100ml iron; 1.7µg/100ml vitamin D) or non-fortified cow's milk (CM) (0.02mg/100ml iron; no vitamin D) for 20 weeks. Blood samples were taken before and after the intervention. ID was defined as serum ferritin (SF) <12µg/l in the absence of infection (defined as high-sensitivity C-reactive protein <10mg/l). VDD was defined as 25-hydroxyvitamin D (25(OH)D) <50nmol/l.

**Results:** Intention-to-treat analysis revealed that YCF preserved iron status (mean estimated SF change  $\pm$  SE: 1.7µg/l  $\pm$  2.4) and improved vitamin D status (25(OH)D change  $\pm$  SE: 17.4nmol/l  $\pm$  2.8). The ID prevalence decreased slightly in the YCF group (14.3% to 13.9%) and increased in the CM group (11.9% to 29.6%) (p=0.036). The VDD prevalence decreased in the YCF group (25.3% to 13.5%) and increased in the CM group (21.9% to 33.3%) (p<0.001).

**Conclusion:** Compared to cow's milk, young child formula use for 20 weeks preserves iron status and improves vitamin D status in healthy young children in Western-Europe.

**Disclosure of interest:** This study was funded by Danone Nutricia Research. The statistical analyses and the interpretation of the data were performed independently from Danone Nutricia Research. Akkermans, Brus and Van Goudoever work in non-profit hospitals in the Netherlands. Van Goudoever is also a member of the National Breastfeeding council, the ESPGHAN council, the National Health council, the neonatal nutrition section of the Dutch Paediatric Association and he is the director of the (Dutch) National Donor Human Milk Bank. He received honoraria for presentations and consultations from Danone, Nutricia, Mead Johnson Nutrition, Nestle, Nutrition Institute, Hipp, Prolacta and Nutrinia. Eussen and Van Elburg are employees and Van der Horst-Graat is a former employee of Danone Nutricia Research.