

Harvey BM, Eussen SRBM, Harthoorn LF, Burks AW. Mineral intake and status of cow's milk allergic infants consuming an amino acid-based formula. *J Pediatr Gastroenterol Nutr.* 2017;65:346-9.

### Abstract

Purpose: A prospective, randomized, double-blind controlled clinical trial assessed the mineral status of term infants, age 0-8 months at recruitment, diagnosed with CMA consuming an amino acid-based formula (AAF) for 16 weeks.

### Methods:

Serum levels of minerals routinely assessed in the target population were measured at baseline (n = 82) and following 16 weeks receiving an AAF, Neocate®, with or without synbiotics (n = 66). Minerals (calcium, phosphorus, chloride, sodium, potassium, magnesium and iron (ferritin)) were analyzed using standard methods, and results were evaluated against reference ranges that were age specific. Individual intakes of estimated energy and minerals were compared to Adequate Intake (AI) levels established by the US Institute of Medicine and European Food Safety Authority.

### Results:

Mean serum mineral levels at baseline and following 16 weeks receiving an AAF were within reference ranges for age. Some individual baseline values were below age-specific reference ranges for calcium, phosphorus, chloride, sodium and ferritin, whereas after 16 weeks only the ferritin level for some individuals remained below the reference range. Mean estimated intakes from formula plus diet for most minerals were above or close to the AIs, suggesting low prevalence of inadequate mineral intakes.

### Conclusions:

Individual mineral levels at week 16 were all within age-specific ranges, with the exception of ferritin. Previous research in healthy infants also found low levels of serum ferritin of similar prevalence. A vast majority of infants 0-6 months (formula as sole source of nutrition) and aged 6-12 months (formula plus complementary foods) had adequate mineral intakes. This study shows that the AAF Neocate, with or without synbiotics, effectively supported adequate serum status of the selected minerals in cow milk-allergic infants.

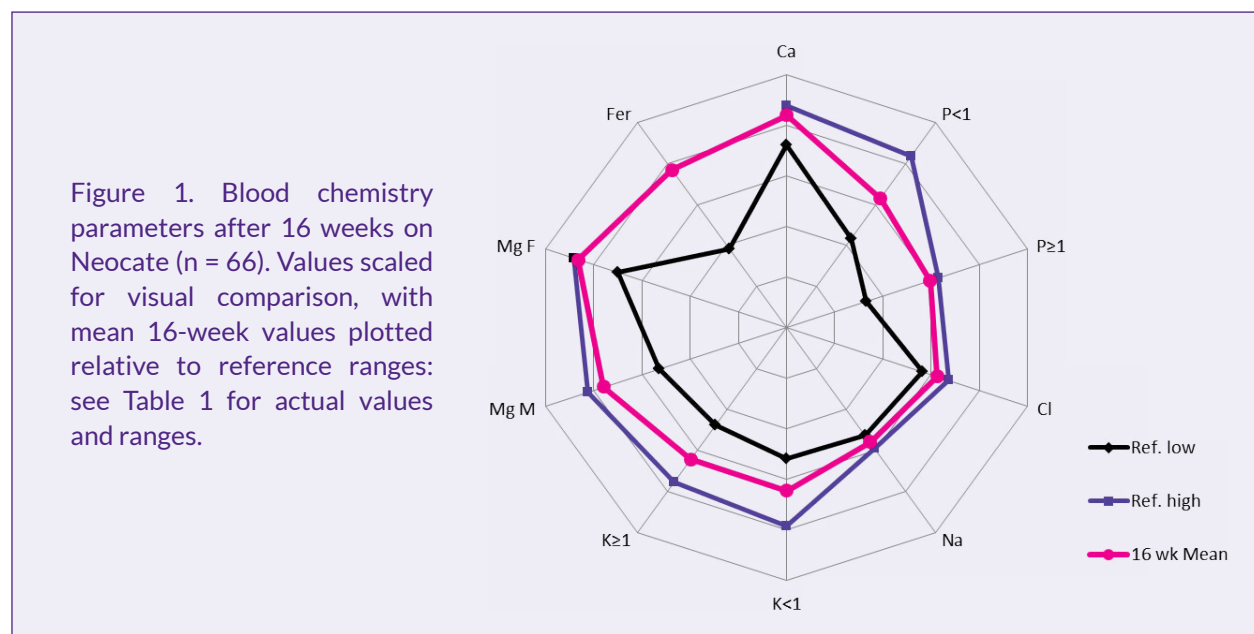


Table 1. Mean blood chemistry parameters after 16 weeks on Neocate (n = 66) and number of subjects with mineral status below the reference range.

Mineral	Reference range	After 16 weeks on Neocate, Mean ± SD	Subjects below reference range after 16 weeks
Calcium (Ca), mmol/L	2.25-2.74	2.62 ± 0.14	n = 0
Phosphorus <1 y (P<1), mmol/L	1.36-2.62	1.97 ± 0.20	n = 0
Phosphorus ≥1 y (P≥1), mmol/L	1.03-1.97	1.86 ± 0.24	n = 0
Chloride (Cl), mmol/L	94-112	104 ± 2.3	n = 0
Sodium (Na), mmol/L	132-147	140 ± 2.3	n = 0
Potassium <1 y (K<1), mmol/L	3.7-5.6	4.6 ± 0.29	n = 0
Potassium ≥1 y (K≥1), mmol/L	3.4-5.4	4.6 ± 0.48	n = 0
Magnesium Male ≥30 d (Mg M), mmol/L	0.66-1.03	0.95 ± 0.07	n = 0
Magnesium Female ≥30 d (Mg F), mmol/L	0.78-0.98	0.96 ± 0.07	n = 0
Ferritin (Fer), mcg/L	≥12	24 ± 18	n = 15*

\*Previous research in healthy infants also found low levels of serum ferritin of similar prevalence.<sup>1</sup>

Figure and table adapted from Harvey et al. 2017.

**This study supports that Neocate® Syneo® Infant and Neocate® Infant\* are effective in providing adequate dietary mineral intake and maintaining mineral status in infants with cow milk allergy.**

**This research adds to the understanding of the nutritional status of infants who consume an amino acid-based formula for the dietary management of cow milk allergy.**

Adapted from publicly available full text article - [https://journals.lww.com/jpgn/Fulltext/2017/09000/Mineral\\_Intake\\_and\\_Status\\_of\\_Cow\\_s\\_Milk\\_Allergic.23.aspx](https://journals.lww.com/jpgn/Fulltext/2017/09000/Mineral_Intake_and_Status_of_Cow_s_Milk_Allergic.23.aspx)

\*Known in the US as Neocate® Infant DHA/ARA and in Canada as Neocate® DHA & ARA infant formula.

1. Eussen, et al. Ann Nutr Metab. 2015;66:80-92.