

Clinical trial shows Neocate Junior's good acceptance and tolerance in children over 1 year of age with cow milk allergy and related conditions

Background:

Dietary management of cow milk allergy (CMA) and related gastrointestinal and allergic conditions requires dietary elimination of food allergens. When these conditions persist into childhood, the long-term dietary restriction can lead to inadequate nutrient intake and poor growth. This study used a longitudinal design to evaluate a nutritionally complete amino acid-based formula (AAF) specifically formulated to have optimal palatability and nutritional profile for patients 1 year of age and older.

Methods:

Patients received the test formula (Neocate® Junior, Unflavored and/or Flavored) for a period of 4 weeks. Adherence was assessed throughout the study by the daily parent/caregiver record of how much formula was received compared to the amount recommended by the RD at baseline. Any changes to this recommendation were noted. Gastrointestinal symptoms were tracked by parents/caregivers using a standardized gastrointestinal tolerance questionnaire at baseline and at days 1, 2, 3, 7, 14, 21, 26, 27 and 28. Formula acceptability was assessed at week 4 by a parent/caregiver completed questionnaire. Nutrient intake and growth parameters, including weight, were documented at baseline and at week 4.

Results:

This prospective study recruited 30 patients from 10 centers in the United Kingdom. Prior to enrollment, patients (average 2 years, 7 months (range 1 year to 8 years, 5 months)) were already using an AAF (n=24) or alternative (breast milk or plant-based beverage, n=6) for dietary management of: 83% food allergies, mostly multiple; 7% food intolerance; 7% reflux and 3% eosinophilic esophagitis.

Average adherence to recommended intake of Neocate Junior throughout the study was high, 92% ($\pm 39\%$, SD). Average recommended formula intake was 510 kcal/day (± 370 , SD) with formula consumed orally by 83% of patients, and for the remaining 17% by tube. Gastrointestinal tolerance and allergic symptoms during use of Neocate Junior remained well managed. A majority of oral patients enjoyed Neocate Junior (taste 68%; texture 72%), and a majority (73%) preferred Neocate Junior to any previous AAF taken.

Intakes were stable for energy (+72 kcal/d vs baseline, NS) and improved over baseline with the test AAF for 16 of 20 vitamins and minerals ($p < 0.02$: zinc, copper, vitamin B2). More patients (76% at week 4 vs. 66% at baseline) met standard recommended intakes (Reference Nutrient Intakes (RNIs)) for at least 15 of 20 vitamins and minerals compared to baseline ($p < 0.04$: zinc 77% vs. 53%; copper 97% vs. 73%; vitamins B2 97% vs. 67% and B6 90% vs. 67%).

For patients not consuming an AAF at baseline (n=6), all micronutrient intakes increased at week 4 except vitamin B12 (-0.1 mcg, NS) ($p \leq 0.05$: magnesium, zinc, copper, folate, pantothenic acid, vitamins D, C, B2 and B3). Also, among this subset, more patients met standard recommended intakes (RNIs) for all 20 micronutrients at week 4 (mean 75%) compared to baseline (9%).

At the completion of the 4 week trial, significant increases in anthropometric outcomes were also documented. Notably, increases were observed for mean weight (+0.41kg; z-score +0.23; p-value ≤ 0.05).

Conclusion:

In this study, children 1 year of age and older with CMA and related gastrointestinal and allergic conditions had excellent adherence to a nutritionally complete, specially formulated AAF. The good acceptance and tolerance by patients helped improve growth and intake of most vitamins and minerals relative to baseline and supported continued dietary management of food allergy symptoms. These data add to the understanding of the use of AAF in children 1 year of age and older. Longer, controlled clinical trials are needed to assess patient outcomes more fully.

This clinical trial in children with food allergies and related conditions shows that:

- Children enjoyed the taste of Neocate Junior
- Children had excellent adherence to recommended intake of Neocate Junior
- Neocate Junior helps support growth

Adapted from the publicly available poster abstract found at <https://onlinelibrary.wiley.com/doi/10.1111/all.13252>

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Study protocol is publicly available at <https://clinicaltrials.gov/ct2/show/NCT02569840>.

Both flavored and unflavored Neocate Junior products were included in this study (internal study report, data on file).

NS = Not significant; SD = Standard deviation

Formulation studied was comparable in composition to Neocate Junior formulation available in US since 2018 and Canada since 2019

Neocate® is a family of hypoallergenic, amino acid-based medical foods. Neocate is intended for use under medical supervision.