PEDIATRIC NUTRITION NEEDS MET WITH A HIGH CALORIE PEPTIDE-BASED ENTERAL FORMULA

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Background:

Children with compromised gastrointestinal function are at increased risk for malnutrition. Malnutrition can have subsequent permanent effects on growth, activity and quality of life. Studies support the benefits of improved tolerance and outcomes in patients that received enteral therapy with a peptide-based diet.

Objectives:

- The purpose of this prospective observational study was to demonstrate ability to meet estimated nutrition goals, by achievement of 90% of caloric goal for at least 14 days, in a pediatric tube-fed population with neurological diagnoses and compromised gastrointestinal function
- Secondary objectives included assessment of formula tolerance, examination of gastrointestinal tolerance parameters, mood and frequency and nature of adverse events

	N (%)
Gender:	
Male	3 (37.5)
Female	5 (62.5)
Feeding Tube Type	
G-tube	8 (100)
	Mean [std]
Age at enrollment (years)*	8.3 [3.7]
Height (cm)	107.9 [12.1]
Weight (kg)	17.6 [7.1]
BMI (kg/m²)	14.5 [2.4]
Primary Diagnoses	Familial Dysautonomia, Global developmental delay, GERD, CP, Mixed dystonia and spastic quadriplegia, Mixed quadriplegic CP, Costello Syndrome, Downs Syndrome, Dyskinetic CP

^{*}mean of 7 subjects

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METHODS

- Tube-fed children (1-13 years) with diagnosis appropriate for a peptide-based diet, established enteral feeding (EN) and anticipated to require EN to provide at least 90% of their nutritional needs for at least 14 days were recruited
- Consented subjects were observed on their Pre-Study Formula (PSF) for 3 days (Day -3 to Day-1)
- Subject nutrition and feeding goals were determined by clinical dietitian based on facility practice
- At study Day 0, study formula (SF) PEPTAMAN Junior[®] 1.5 (Nestlé Health Science, Bridgewater, NJ) was initiated
- Each subject was fed for another 21 days (Day 1-21)
- Caregivers assessed gastrointestinal tolerance measures (stool frequency/consistency, vomiting, gas and abdominal pain), mood and general health on Days -3 to -1, 1-3, 10-12, and 19-21
- Physician assessment of tolerance measures was completed at final visit
- All data analyses were conducted using descriptive statistics. Means, standard deviations, minimum and maximum values calculated for continuous data, and counts and percentages calculated for categorical data

RESULTS

- Eight children consented and participated in study. Subject demographics described in Table 1
- Calorie & protein intake increased between PSF and SF (1085 vs 1354 kcals/d; 36 vs 41 g/d, respectively) (Figure 1)
- Five subjects met at least 90% of calorie goal on SF; 3 subjects met 73-81% of goal; 100% met protein goal
- Formula was well tolerated based on caregiver report, with no change in gastrointestinal events (Figure 2)
- Stool consistency was reported most frequently as 'Soft' for both PSF and SF (Figure 2)
- Caregiver reported subject mood as "happy" or "content" the majority of the time
- No product related serious adverse events reported

Figure 1: Daily Percentage of Nutritional Goals Met

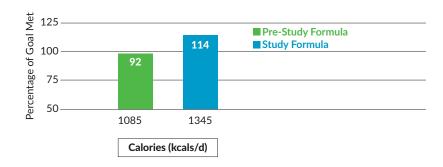
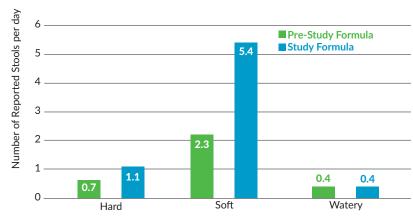


Figure 2: Stool Characteristics*



^{*} Pre-study 3 day average. Study formula 9 day average.

CONCLUSION

- Calorically-dense, peptide-based whey enteral formula was associated with an increase in nutritional intake in children with neurological diagnoses and GI disorders
- · Formula was well tolerated
- Data adds to existing evidence demonstrating the benefit of peptide-based formulas in pediatric population with compromised gastrointestinal function