Tolerance and Safety of a Peptide-based Enteral Formula with Partially Hydrolyzed Guar Gum (PHGG) in Tube-fed Children Aged 1-4 Years: An Open-label, Single-arm Study

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BACKGROUND

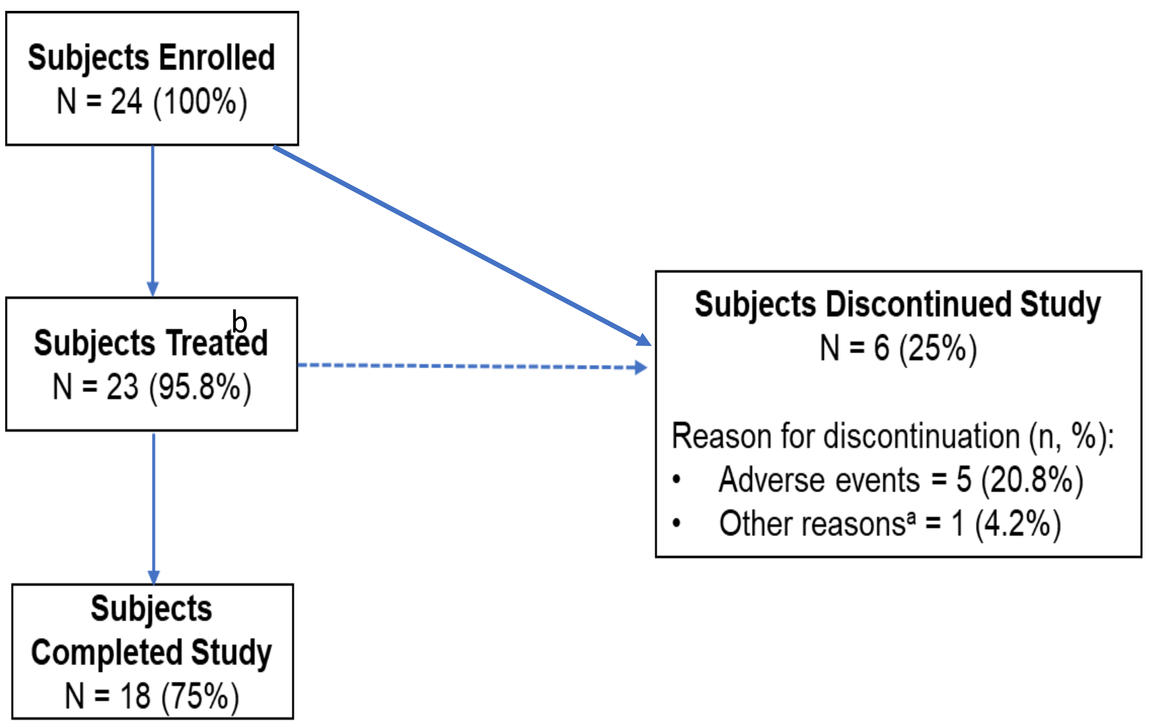
- Partially hydrolyzed guar gum (PHGG) is a water-soluble, non-viscous fiber produced by partial enzymatic hydrolysis of guar gum seeds [1].
- The safety and efficacy of PHGG have been reported in several clinical studies in children and adults with constipation or diarrhea [1,2].
- Enteral nutrition can be associated with gastrointestinal adverse effects, such as diarrhea and constipation, which may impact the quality of life of tube-fed children.
- This study aimed to assess the tolerability and safety of an enteral formula containing PHGG at 12 g/L when provided as the main source of nutrition in tube-fed children aged 1–4 years.

METHODS

- A multi-center, open label, single-arm study was conducted in 3 pediatric gastroenterology centers in the USA.
- Children aged 12 to 48 months requiring enteral tube feeding to provide ≥ 80% of their nutritional needs for at least 7 days were included.
- The study formula (Peptamen Junior PHGG®; Nestlé Health Science, Switzerland) was a whey-based, semi-elemental formula supplemented with PHGG 12 g/L, providing 1.2 kcal/mL of energy.
- The study formula was given via gastrostomy for a 7-day period.
- Gastrointestinal tolerance, adverse events, weight change and energy/protein intake were assessed.

RESULTS

FIGURE 1: Summary of Subject Disposition



(a) One subject was excluded after enrollment, prior to receiving any study treatment, due to age > 48 months
(b) Modified Intention To Treat (mITT) and Per-Protocol (PP) population were identical (n= 23)

Table 1: Summary of Demographics and Baseline Data

Baseline Characteristics	Number of Subjects Total, N=24
Age, median (range), months	35.5 (16, 57)
Sex, female, n (%)	10 (41.6)
Primary diagnoses, n (%)	
• History of extreme prematurity	14 (58.3)
• Genetic conditions	4 (16.6)
• Hypoxic ischemic encephalopathy	3 (12.5)
• Feeding disorder of unknown etiology	3 (12.5)
Gastrointestinal comorbidities, n (%)	
• Constipation	17 (70.8)
• Treatment for gastroesophageal reflux/vomiting	16 (66.6)
Weight-for-age z-score, median (range)	-0.7 (-3.2, 1.4)
Length-for-age z-score, median (range)	-2.0 (-4.7, 1.4)
Weight-for-length z-score, median (range)	0.4 (-3.1, 3.1)

- ✓ **The study formula was well tolerated : 82.6% (19/23) of subjects had no gastrointestinal adverse effects leading to discontinuation of the formula**
- ✓ **Energy and protein requirements were met**
- ✓ **Weight was maintained during the 7-day period (median change in weight-for-age of -0.04 SD; p = 0.4)**

Table 2: Summary of Stool Characteristics

Stool Characteristics	
Number of stools per day, mean (SD)	
• Day 1	1.2 (1.1)
• Day 7	1.8 (1.2)
Subjects with no bowel movements for 24 hours, n (%)	
• Day 1	9/23 (39.1)
• Day 7	3/18 (16.7)
Subjects with constipation*, n (%)	
• Day 1	4/23 (17.4)
• Day 7**	0 (0)
Subjects who stopped laxatives during the 7-day trial, n (%)	3/16 (18.7)
Subjects with diarrhea***, n (%)	5/23 (21.7)

**Defined as stools of Bristol Stool Scale type 1 or 2; **No cases of constipation from Day 4 ***Defined as 3 watery stools (Bristol Stool Scale type 7) per day*

Table 3: Summary of All Treatment Emergent Adverse Events

Treatment Emergent Adverse Events (TEAE)	Total, N=23	
	Events, n	Subjects, n (%)
Overall	31	12 (52.1)
○ Gastrointestinal disorders*	22	11 (47.8)
• Abdominal pain	5	4 (17.4)
• Flatulence/malodorous stool	2	2 (8.6)
• Diarrhea	5	5 (21.7)
• Vomiting	10	9 (39.1)
○ Non-Gastrointestinal disorders (infections, irritability, hiccups, rhinorrhea)	9	8 (34.7)
Serious Adverse Events**	2	1 (4.3)
TEAE Leading to Study Discontinuation	7	5 (21.7)
TEAE 'Related' or 'Probably related' to the study product**	8	3 (13)

**Gastrointestinal TEAE were more common in fiber-naïve children or those receiving laxative treatment*
***No serious adverse events were related to the study formula*

KEY MESSAGES

- ✓ **The partially hydrolysed, whey-based formula with PHGG was well tolerated in tube-fed children aged 1-4 years, with a shift to softer and more regular stools.**
- ✓ **The formula may support constipation management and reduce the need for laxatives in tube-fed children.**
- ✓ **To reduce the risk of gastrointestinal intolerance in young children, a gradual introduction should be considered, particularly in fiber-naïve children or those receiving laxative treatment.**

REFERENCES

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2. Romano C, et al. Fibers in pediatric functional gastrointestinal disorders. Practical considerations from clinical cases. Expert review of gastroenterology & hepatology. 2021.

Conflict of interest: KR, AS, RH and BZ are employees of Nestle Health Science