Nestlé HealthScience

PEPTAMEN® Junior PHGG

Tolerability and Safety of a Semi-Elemental Enteral Formula with Partially Hydrolyzed Guar Gum (PHGG) in Tube-Fed Children Aged 1–4 Years: *An Open-Label, Single-Arm Study**

Materials & methods

A multicenter, open-label, single-arm study was conducted in **three pediatric gastroenterology centers**.

Administered formula for the study:

Continous or bolus feeding via a nasogastric tube or feeding gastrostomy

Partially hydrolyzed whey formula

12g/L of PHGG fiber

24 children

For **7** days

1 to 4 years requiring tube feeding to provide ≥80% of their nutritional needs

All children had underlying neuro-developmental disabilities

70.8% requiring treatment for constipation

66.7% requiring treatment for gastro-esophageal reflux

Main results

- **82.6%** of subjects **tolerate** the fomula **well**
- **103.5% energy** intake across the **7-day** period
- **139.5% protein** intake across the **7-day** period
- Weight remained **stable over the 7-day** period (p=0.43)
- Shift towards **softer** and more frequent stools
- Pre-existing constipation was **generally well controlled**
- **18.7%** subjects ceased laxatives during the study
- **Stool characteristics**
  Starting from Day 4, no participant experienced very hard or hard stools (Bristol Stool Scale type 1 or 2). The percentage of subjects with normal stools went from **21.8% on Day 1** to **38.9% on Day 7**.

Discussion

Constipation was well controlled in all children within **3 days of formula intake**. PHGG **increases fecal moisture** and **output**,[1,2,3,4] which promotes colonic peristalsis and **facilitate defecation**.[5]

PHGG intake in the present study, which averaged 12 g/day, is aligned with the recommendations. The study product has one of the **highest fiber contents, among currently available pediatric enteral nutrition formulas**. Fiber-naïve children, or those usually consuming low-fiber diets, may benefit from a **gradual introduction of fiber**, including PHGG. This approach may **facilitate progressive gastrointestinal adaptation** and **less risk** for developing gastrointestinal intolerance symptoms.[6]

Conclusions

This is the first study to assess the **safety and tolerability of a PHGG-enriched formula** in **young tube-fed children aged 1–4 years**. The study formula was generally **well tolerated** and **provided adequate nutrition**. The formula was associated with a **shift towards softer** and **more frequent stools** in a population with a high prevalence of constipation. Therefore, the formula may have a role in the clinical management of chronic constipation and may enable a reduction in laxative treatment in some patients. A **gradual introduction of the formula may reduce the risk of gastrointestinal intolerance symptoms**, especially among 'fiber-naïve' patients.

*G. Minor, T. Sentongo, R.G. Heine *et al.* Tolerability and safety of a semi-elemental enteral formula with partially hydrolyzed guar gum (PHGG) in tube-fed children aged 1-4 years: An open-label, single-arm study. Clinical Nutrition ESPEN 55 (2023) 392e399.

1. Giannini EG, Mansi C, Dulbecco P, Savarino V. Role of partially hydrolyzed guar gum in the treatment of irritable bowel syndrome. Nutrition 2006;22(3): 334e42. **2.** Takahashi H, Wako N, Okubo T, Ishihara N, Yamanaka J, Yamamoto T. Influ-ence of partially hydrolyzed guar gum on constipation in women. J Nutr Sci Vitaminol 1994;40(3):251e9. **3.** Cummings JH, Branch W, Jenkins DJ, Southgate DA, Houston H, James WP. Colonic response to dietary fibre from carrot, cabbage, apple, bran. Lancet 1978;1(8054):5e9. **4.** Takahashi H, Yang SL, Hayashi C, Kim M, Yamanaka J, Yamamoto T. Effect of partially hydrolyzed guar gum on fecal output in human volunteers. Nutr Res 1993;13:649e57. **5.** Pylkas AM, Juneja LR, Slavin JL. Comparison of different fibers for in vitro production of short chain fatty acids by intestinal microflora. J Med Food 2005;8(1):113e6. **6.** Lionetti et al. Use of fiber-containing enteral formula in pediatric clinical practice: an expert opinion review. Expert Review of Gastroenterology & Hepatology, DOI: 10.1080/17474124.2023.2217355.