

# 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:

Continuous 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 formula 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,<sup>1,2,3,4</sup> which promotes colonic peristalsis and facilitate defecation.<sup>5</sup>

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.<sup>6</sup>

## 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.

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