GASTROINTESTINAL TOLERANCE AND EASE OF USE OF A NEW MILDLY THICK ORAL NUTRITIONAL SUPPLEMENT WITH AMYLASE RESISTANCE FEATURES

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INTRODUCTION

Dysphagia can impair oral feeding, causing malnutrition, dehydration, and aspiration (1). A common therapy is diet modification aimed at increasing bolus viscosity (2). This includes manual thickening of Oral Nutritional Supplements (ONS), which may be difficult and time-consuming (3). For this reason Nutricia developed a pre-thickened, mildly-thick α-amylase resistant energy-dense ONS with multi-fibres (AR). The aim of this randomized controlled open label study was to compare the gastrointestinal (GI) tolerance of ready-to-use AR with a standard ONS manually thickened to the same consistency using a thickener (C).

METHODS

Study population
- 50 patients in need of oral nutritional support of at least 300 kcal/day of energy enriched ONS, prescribed by a healthcare professional. 48% of the subjects were diagnosed with oropharyngeal dysphagia and required thickened drinks with a stage-1 consistency.
- Recruited in care homes, hospitals, and general practices in Ireland, Germany, and the Netherlands.

Study design
- Randomised, controlled, open label.
- 1-day baseline on current regimen.
- 28-day intervention on a new pre-thickened ONS with multi-fibres Nutrilis Complete™ (AR) or standard ONS Fortisip Multifibre™ manually thickened with a commercially available thickener (C).

Diet regimen
- At least one bottle of pre-thickened ONS (AR) or standard ONS thickened with commercially available thickener (C) per day.
- Food and drinks according to patient’s normal care.

Outcome parameters

Primary parameters
- GI tolerance parameters (at baseline, day 14, and day 28)
- Stool frequency (daily)

Other parameters
- Daily study product intake (kcal/day and % prescribed)
- Total food and fluid intake (baseline, day 14, and day 28)
- Body weight and BMI (baseline, day 14, and day 28)
- Product appreciation (day 14, and day 28)
- Product evaluation by carer (Day 28)
- Safety parameters
- (Serious) adverse events.

Statistics
- One-way ANOVA or Fisher’s Exact test (α=0.050, two-sided test).

RESULTS

Subgroup analyses showed similar results for the dysphagia group and the total study group.

No statistically significant differences were found in daily stool frequency and in incidence and intensity of seven GI symptoms (nausea, vomiting, diarrhoea, constipation, abdominal distension (bloating), belching, and flatulence) between AR and C. Furthermore there were no safety issues based on adverse events.

For the total intervention period no significant differences were found in fluid intake and in total dietary intake between AR and C for the total study group. However, for AR a significant increase of intake of total energy, carbohydrate, protein, and fat was found in time (day 28 – baseline; P<0.005). For the Control product no change in dietary intake was found in time.

No significant differences were found in body weight and BMI between AR and C.

<table>
<thead>
<tr>
<th></th>
<th>AR product Mean ± SEM (n)</th>
<th>Control product Mean ± SEM (n)</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Body weight (kg)</td>
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<tr>
<td>Baseline</td>
<td>56.5 ± 2.6 (26)</td>
<td>56.9 ± 2.8 (22)</td>
<td>0.371</td>
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<tr>
<td>Day 14</td>
<td>57.5 ± 0.4 (19)</td>
<td>57.7 ± 0.4 (20)</td>
<td>0.711</td>
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<tr>
<td>Day 28</td>
<td>57.3 ± 0.6 (19)</td>
<td>57.9 ± 0.6 (16)</td>
<td>0.446</td>
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</table>

Subjects in the AR group scored the consistency of the product more positively than the control group (P=0.035).

Conclusions: Caregivers evaluated the ready-to-use AR product significantly more positively than the Control for appearance (P=0.049), preparation time (P<0.0001), ease of preparation (P<0.0001), and stability of thickness (P<0.0001).

CONCLUSION

This study shows that this new ready-to-use AR product is well-tolerated. Furthermore it is easier to administer and has a more stable consistency over time.

Therefore, this pre-thickened AR product supports a safe and easy use in patients with dysphagia.

REFERENCES