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Topic area: 5. NUTRITION

Topic: 5.2. Nutrients and gut function

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XYLOGLUCAN AND GELATIN FOR THE TREATMENT OF ACUTE GASTROENTERITIS IN CHILDREN: RESULTS OF A RANDOMIZED, CONTROLLED, OPEN-LABEL, PARALLEL GROUP, MULTICENTRE, NATIONAL CLINICAL TRIAL

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Introduction: Gelatin or xyloglucan are currently used for gastroenteric disorders, although data from randomized studies are needed to completely assess the efficacy of these products in acute diarrhea or acute gastroenteritis in different types of patients.

Aims & Methods: To assess the efficacy, safety and time of onset of the antidiarrheal effect of xyloglucan and gelatin (Tasectan Plus®, containing xyloglucan and gelatin of animal origin) in children with acute gastroenteritis receiving oral rehydration solution (ORS).

This randomized, controlled, open-label, parallel group, multicentre, clinical trial included children (from 3 months to 12 years old) with acute gastroenteritis of infectious origin.

Children were randomized to receive a 5-day treatment. Both control and active groups received ORS and active group also received Tasectan Plus® (one sachets/8 hours in children younger than 3 years and 2 sachets/8 hours in children between 3 and 12 years). Diarrheal symptoms and safety were assessed in 3 visits (baseline, at 2 and 5 days) and by phone call at 10 days, and by fulfillment of a diary card by the parents or legal representatives.

The number and characteristics of stools (type 6 and 7 on Bristol Scale) and the evoluation of other diarrheal symptoms (nausea, vomiting, abdominal pain, flatulence, fever and dehydration) were assessed during the 72 hours previous to baseline and, after inclusion, at 24-hour intervals (during the first day of treatment assessments were performed at 1, 3, 6, 12 and 24 hours). Occurrence of adverse events was recorded during the whole study period.

Results: A total of 36 patients (58.3% girls; age: 13.9% ≤ 1 year, 47.2% 1-5 years, 25.0% 5-10 years, 13.9% >10 years) were included (n = 18 in each group). The group treated with xyloglucan/gelatin and ORS had a better evolution in almost all parameters than the group receiving ORS alone. A faster onset of action was observed in the xyloglucan/gelatine group compared with the control group, since at 6 hours, xyloglucan/gelatin produced a statistically significant higher decrease in the number of type 7 stools (0.11 vs 0.44; p=0.027). At days 3 and 5, xyloglucan/gelatin was also able to produce a statistically significant higher reduction of type 6 and 7 stools in comparison with ORS alone (p=0.026 and 0.034, respectively). A better evolution fro nausea, vomiting and abdominal pain was also recorded for the xyloglucan/gelatin group, although the differences vs the control group were not statistically significant. Xyloglucan/gelatin plus ORS was safe and well tolerated, without the occurrence of adverse events throughout the study.

Conclusion: Xyloglucan/gelatin is a fast, efficacious and safe option for the treatment of acute gastroenteritis in children, with a rapid onset of action in reducing diarrheal symptoms.

I confirm having declared any potential Conflict of Interest for ALL authors listed on this abstract: Yes