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Xyloglucan 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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1 Introduction

Film-forming agents as 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.

2 Specific objective

To assess the efficacy, safety and time of onset of the antidiarrheal effect of xyloglucan in children with acute gastroenteritis receiving oral rehydration solution (ORS).

3 Patients and Methods

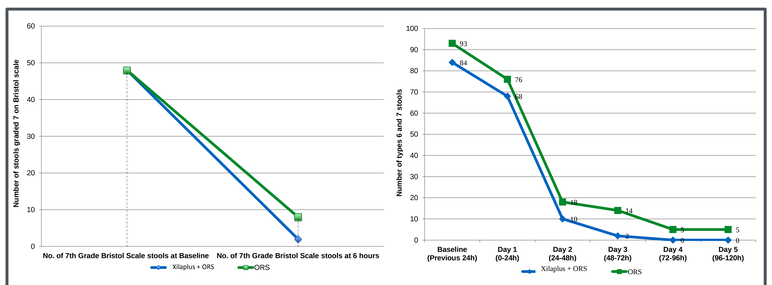
This randomized, controlled, open-label, parallel group, multicentre, clinical trial included children (from 3 months to 12 years old) with acute gastroenteritis of infectious origin.

Children were randomized to receive a 5-day treatment. Both control and active groups received ORS and active group also received xyloglucan (Xilaplus®) (one sachet/8 hours in children younger than 3 years and 2 sachets/8 hours in children between 3 and 12 years). Diarrheal symptoms, including number and characteristics of stools (on Bristol scale), and safety were assessed in 3 visits (baseline, at 2 and 5 days), and by fulfillment of a diary card by the parents.

4 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 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 group compared with the control group (Figures 1 and 2). At 6 hours, xyloglucan produce a statistically significant higher decrease in the number of type 7 stools (0.11 vs 0.44; p = 0.027) (Figure 1A).

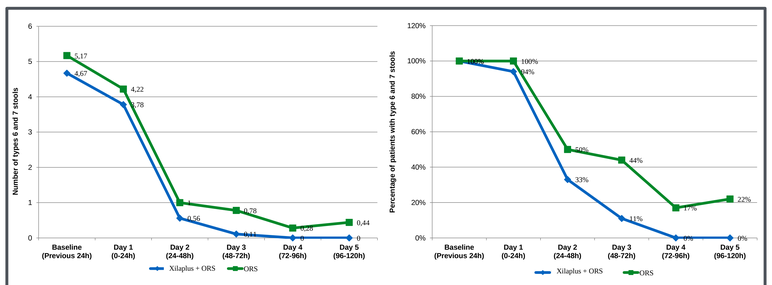


A) Evolution of the absolute number of type 7 stools during the first 6 hours.

B) Evolution of absolute number of type 6 and 7 stools during the study period.

Figure 1. Evolution of dehydrating stools in both groups.

In comparison with the control group, the percentage of patients with type 6 and 7 stools was always lower in the xyloglucan group from day 1 to day 5, being statistically significant at days 3 and 5 (p = 0.026 and 0.034, respectively) (Figure 2B).



A) Evolution of mean number of type 6 and 7 stool during the study period.

B) Evolution of the percentage of patients with type 6 and 7 stools during the study period.

Figure 2. Evolution of dehydrating stools in both groups.

At days 3 and 5, xyloglucan was also able to produce a statistically significant higher reduction of type 6 and 7 stools in comparison with ORS alone (Figures 1B and 2A).

A better evolution of nausea, vomiting and abdominal pain was also recorded for the xyloglucan group (Figure 3). Xyloglucan plus ORS was safe and well tolerated, without the occurrence of adverse events throughout the study.

A) Evolution of the percentage of patients with nausea.

B) Evolution of the percentage of patients with vomiting.

C) Evolution of the percentage of patients with abdominal pain.

D) Evolution of the percentage of patients with flatulence.

Figure 3. Evolution of clinical symptoms of gastroenteritis during the study period in both groups.

5 Conclusions

Xyloglucan 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.

Conflict of interest

All authors received honoraria from Novintethical Pharma SA to perform the study.