

# UEG Week 2015 - Abstract Submission

Topic area: 5. NUTRITION

Topic: 5.2. Nutrients and gut function

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## **XYLOGLUCAN FOR THE TREATMENT OF ACUTE DIARRHEA: RESULTS OF A RANDOMIZED, CONTROLLED, OPEN-LABEL, PARALLEL GROUP, MULTICENTRE, NATIONAL CLINICAL TRIAL**

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**Introduction:** There is a strong rationale for the use of agents with film-forming protective properties, like xyloglucan, for the treatment of acute diarrhea. However, few data from clinical trials are available.

**Aims & Methods:** To assess the efficacy, safety and time of onset of the antidiarrheal effect of xyloglucan (Xilaplus<sup>®</sup>), in comparison with two widely used anti-diarrheal agents, the yeast probiotic *Saccharomyces boulardii* (Ultra-Levura<sup>®</sup>), and diosmectite (Smecta<sup>®</sup>), an absorbent activated natural aluminosilicate clay.

This randomized, controlled, open-label, parallel group, multicentre, clinical trial included adult patients with acute diarrhea due to different causes.

Patients were randomized to receive a 3-day treatment (4 capsules/6 h of Xilaplus<sup>®</sup>, 3 sachets/day of Smecta<sup>®</sup> and 2 capsules/day of Ultra-Levura<sup>®</sup>), being the first dose administered at visit 1. Presence of symptoms (stools type 6 and 7 on Bristol Scale, nausea, vomiting, abdominal pain and flatulence) was assessed by a self-administered *ad-hoc* questionnaire at 1, 3, 6, 12, 24, 48 and 72 h after the first dose administration. Adverse events were recorded.

**Results:** 150 patients (69.3% women, mean age 47.3 ± 14.7 years) were included (n = 50 in each group). A faster onset of action was observed in the xyloglucan group compared with diosmectite group, in terms of absolute and mean number of stools (p<0.05) during the first 24 h. In the xyloglucan group the highest reduction of the number of type 6 and 7 stools was observed at 6 h with an effect that was statistically significant compared with diosmectite (p = 0.031). A higher efficacy was also observed with xyloglucan compared to *S. boulardii* at 12 and 24 h.

Xyloglucan was the most efficient treatment in reducing nausea throughout the study, particularly during the first hours (from 26% at baseline to 4% after 6 and 12 h).

An important improvement of vomiting was observed in all three treatment groups, with null percentages at 6 and 12 h.

Xyloglucan was more effective than diosmectite and *S. boulardii* in reducing abdominal pain, with a constant improvement observed throughout the study. At visit 2, the lowest percentage of patients with abdominal pain was recorded in the xyloglucan group (10%), in comparison with diosmectite (22%) and *S. boulardii* (12%).

The clinical evolution of flatulence followed similar patterns in the 3 groups, with continuous improvement of the symptom. The greatest improvement was shown in the xyloglucan group, with 10% of patients with flatulence at visit 2, compared with diosmectite (30%) and *S. boulardii* (18%).

All 3 treatments were well tolerated, without adverse events.

**Conclusion:** Xyloglucan is a fast, efficacious and safe option for the treatment of acute diarrhea, 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**

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