2011. FOS-CD

RCT/Fructo-oligosaccharides/CD/ Induction

Randomised, double-blind, placebo-controlled trial of fructo-oligosaccharides in active Crohn's disease

Double-blind, placebo-controlled, randomized trial.
Patients with active Crohn's disease (CDAI=>220 and an additional marker of indlammation elevated either RP, ESR/platelet count) were randomized to 15g/day fructo-oligosaccharides (FOS) or placebo for 4 weeks.
Anti TNF not allowed but 5ASA, immunosupressants and steroids (max dose 20mg/d) if dose stable for 4 weeks were allowed.

Primary endpoint: Clinical response at week 4 (defined as fall in CDAI of >=70 points)

Results: N=103

- More patients receiving FOS than placebo withdrew before the 4 week end point 26% vs 8% respectively, p=0.018.
- ITT analysis did not show differences between FOS and placebo, 22% vs 39%, p=0.067 respectively.
- Patients taking FOS had reduced IL-6-positive lamina propria dendritic cells and increased dendritic cells staining IL-10, p<0.05
- No differences in IL-12p40 and F. prausnitzii between the groups.

Conclusion:
An adequately powered placebo-controlled trial of FOS showed no clinical benefit in patients with active Crohn's disease, despite impacting on DC function.

Table 2 Response and remission rates in the fructo-oligosaccharide (FOS) and placebo groups

	FOS	Placebo	p Value
Response*			
Intention to treat, n (%)	12 (22%)	19 (39%)	0.067
Per protocol, n (%)	12 (30%)	19 (42%)	0.243
Remission†			
Intention to treat, n (%)	6 (11%)	10 (20%)	0.193
Per protocol, n (%)	6 (15%)	10 (22%)	0.395

Results of χ^2 tests.
*Response: primary end point (reduction in Crohn's Disease Activity Index (CDAI) ≥70 points).
†Remission: CDAI ≤150.

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