Prospective, multicenter randomized trial.

Patients with Crohn's disease who underwent surgery were randomised to synbiotic 1 per day.or placebo. Synbiotic 2000 is a cocktail containing 4 probiotic species and 4 prebiotics:1010 Pediacoccus pentoseceus, 1010 L. raffinolactis, 1010 L. Paracasei susp paracasei 19, and 1010 L. plantarum 2362; the fermentable fibers: 2.5 g β -glucans, 2.5 g inulin, 2.5 g pectin,& 2.5 g resistant starch

<u>Primary endpoints:</u> Endoscopic and clinical relapse at 24 months. *Interim analysis revealed no benefit of active arm so enrollment was stopped.

Results: N=30

- No differences in endoscopic and clinical relapse at 24 months.
- Enrollment was stopped due to lack of efficacy of active arm.

Conclusion:

A single dose of the synbiotic 2000 regiment was found ineffective in preventing postsurgical recurrence of CD.

Table 2 Follow-Up of Patients Treated With Either Synbiotic 2000 or Placebo

	Placebo				Active Treatment				
	0	3	12	24	0	3	12	24	
[Weight] Months mean ± SD	64 ± 17	67 ± 17	76 ± 17	76 ± 30	65 ± 13	68 ± 13	72 ± 14	71 ± 12	NS
Patients (n)	10	8	4	2	20	18	7	8	
Erythrocyte sedimentation rate $(N < 8 \text{ mm/h})$	31	25	0	10	49	21	13	21	
Patients (n)	8	5	0	1	12	13	4	5	
C-reactive protein ($N < 5 \text{ mg/L}$)	1.9	2.2	2.7	0	5.7	4.3	5.3	2.0	NS
Patients (n)	5	6	3	0	7	16	4	4	
Hemoglobin ($14 < N < 18 \text{ g/dL}$)	11.6	12.7	14.2	13.4	11.6	12.7	13.3	12.9	NS
Patients (n)	10	8	4	2	20	19	9	8	
Albumin $(3.5 < N < 5.5 \text{ g/dL})$	3.2	4.0	4.2	4.4	3.3	4.0	4.1	4.0	NS
Patients (n)	10	8	2	2	19	19	8	7	
Abdominal pain ^a	<1	<1	<1	<1	<1	<1	<1	<1	NS
Patients (n)	9	7	3	3	20	19	8	7	
Bowel movements (n)	3	3	2	2	~4	~4	~4	~3	NS
Patients (n)	9	8	4	2	18	19	10	9	
Rutgreets score at 3 mos	0.8	1	0.6	1.7	NS				
Patients (n)	6	1	15	7					
Crohn's disease activity index at 3 mos	102	72	54	110	NS				
Patients (n)	7	1	15	3					

^aAbdominal pain on a 0–3 score scale.

