

Multicenter, double-blind, randomised, placebo-controlled trial. Adult patients with UC were randomised to either fecal microbiota transplantation (FMT) or placebo colonoscopic infusion, followed by enemas 5 days per week for 8 weeks.

FMT were each derived from between 3-7 unrelated donors.

Primary endpoint: Steroid-free clinical remission with endoscopic remission or response at week 8.

Results: N=85

- SF clinical remission+Endoscopic at w8: 27%FMT vs 8%placebo, p=0.021
- SF clinical remission w8: 44%FMT vs 20%placebo, p=0.021
- SF endoscopic remission: 12% FMT vs 8%placebo, p=ns
- Significant differences in microbial profiles were observed.
- Adverse events 78% FMT vs 83% placebo

Conclusion:

Intensive-dosing, multidonor, FMT induces clinical remission & endoscopic improvement in active UC and is associated with distinct microbial changes that relate to outcome.

	Faecal microbiota transplantation (n=41)	Placebo (n=40)	Risk ratio (95% CI)	p value
Primary outcome				
Steroid-free clinical remission and endoscopic remission or response*	11 (27%)	3 (8%)	3.6 (1.1-11.9)	0.021
Secondary outcomes				
Steroid-free clinical remission†	18 (44%)	8 (20%)	2.2 (1.1-4.5)	0.021
Steroid-free clinical response‡	22 (54%)	9 (23%)	2.4 (1.3-4.5)	0.004
Steroid-free endoscopic remission§	5 (12%)	3 (8%)	1.6 (0.4-6.4)	0.48
Steroid-free endoscopic response¶	13 (32%)	4 (10%)	3.2 (1.1-8.9)	0.016

* Total Mayo score ≤2, with all subscores ≤1, and ≥1 point reduction from baseline in endoscopy subscore.

† Combined Mayo subscores of ≤1 for rectal bleeding plus stool frequency. ‡ Decrease of ≥3 points or ≥50% reduction from baseline (or both) in combined Mayo subscores for rectal bleeding plus stool frequency. § Mayo endoscopy subscore 0. ¶ Mayo endoscopy subscore ≤1, with ≥1 point reduction from baseline.

Table 2: Primary and secondary outcomes at week 8

