

Addition of Metronidazole to Azathioprine for the Prevention of Postoperative Recurrence of Crohn's Disease: A Randomized, Double-Blind, Placebo-Controlled Trial

Multicenter, double-blind, randomized trial. Patients with Crohn's disease undergoing ileal or ileocolonic or ileorectal anastomosis were randomized to 2-2.5mg/kg/d azathioprine plus 15-20mg/kg/d of metronidazole or azathioprine and placebo

Primary endpoint: Absence of endoscopic recurrence (Rutgeerts <2) at 6 months

Results: N=50

- Endoscopic recurrence at 6 months AZA+METRO 28% vs AZA+pbo 44%, p=0.19
- Endoscopic recurrence at 12 months AZA+METRO 36% vs AZA+pbo 56%, p=0.15

Conclusion:

The addition of metronidazole to azathioprine did not significantly reduce the risk of endoscopic recurrence beyond azathioprine alone in this study but does not worsen its safety profile

TABLE 3. Differences in Endoscopic Recurrence and Severe Endoscopic Recurrence Between the 2 Treatment Arms (as PP)

	Recurrence Rate With Metronidazole (95% CI)	Recurrence Rate With Placebo (95% CI)	ARR (95% CI)	P
Endoscopic recurrence				
6 months	22% (7 to 44)	36% (17 to 59)	14% (-12 to 41)	0.23
12 months	30% (13 to 53)	50% (28 to 72)	20% (-9 to 48)	0.15
Severe endoscopic recurrence				
6 months	17% (5 to 39)	27% (11 to 50)	10% (-14 to 34)	0.33
12 months	22% (7 to 44)	36% (17 to 59)	14% (-12 to 41)	0.23

