

Phase 3, multicentre, randomised, superiority study. Patients with ileocolonic resection due to Crohn's disease were randomized to AZA 2.5mg/kg/day or Adalimumab 160-80-40mg SC both associated to metronidazole.

Primary endpoints: Endoscopic recurrence at 1 year (Rutgeerts i2b, i3 and i4)

Results: N=84

- Endoscopic recurrence at 52 weeks, AZA 59% vs ADA 42.2%, $p=0.12$
- No differences between MRI, biological markers of activity or hospital admissions between groups.
- Treatment was discontinued due to adverse events more frequently in AZA 13.1% vs ADA 4.4%, $p=0.011$

Conclusion:

ADA has not demonstrated a better efficacy than AZA [both associated with metronidazole] for prophylaxis of POR-CD in an unselected population, although tolerance to ADA is significantly better.

Adalimumab vs Azathioprine in the Prevention of Postoperative Crohn's Disease Recurrence. A GETECCU Randomised Trial

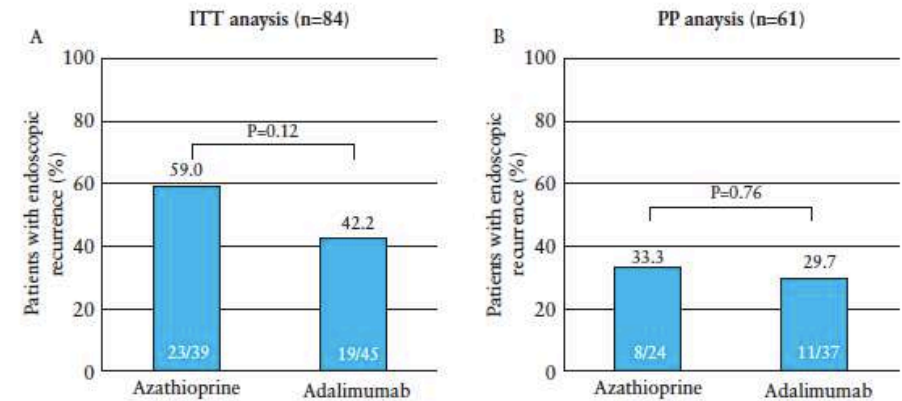


Figure 2. Primary endpoint. The percentages of patients with endoscopic recurrence in the colonoscopy at Week 52 are shown for azathioprine and adalimumab [both associated with metronidazole] in Panels A (intention-to-treat [ITT] analysis) and B (per-protocol [PP] analysis). Incomplete ileoscopy was scored as treatment failure. The Rutgeerts endoscopic grades i2b, i3, and i4 were considered indicative of endoscopic recurrence. The reported p -values are from two-sided tests.