

Placebo-controlled, double-blind, randomized trial.
Patients with active CD (CDAI= \geq 200) were randomized to 2 years
(with a further year of follow-up) of clarithromycin 750mg/d,
rifabutin 450mg/d and clofazimine 50mg/d or placebo, in addition
to a 16-w tapering course of steroids.
5ASA and immunosuppressants at stable dose were permitted.

Primary endpoint: Relapse at 12, 24 and 36 months.

Results: N=213 (entered maintenance phase for analysis n=122)

- At week 16, there were significantly more subjects in remission in the antibiotic arm 66% vs placebo 50%, $p=0.02$
- Of the n=122 subjects entering maintenance phase, 39% on the antibiotic group vs 56% placebo, $p=0.054$ experience at least 1 relapse between w16-52.
- At week 104 26% on antibiotics vs 43% placebo, $p=0.14$
- During the following year 59% antibiotic group vs 50% placebo, $p=0.54$ relapsed.

Conclusion:

Combination antibiotic therapy with clarithromycin, rifabutin & clofazimine for up to 2 years, we did not find evidence of sustained benefit. This finding does not support a significant role for *Mycobacterium avium* subspecies paratuberculosis in CD's pathogenesis in the majority of patients. Short-term improvement was seen when this combination was added to corticosteroids, most likely because of nonspecific antibacterial effects.

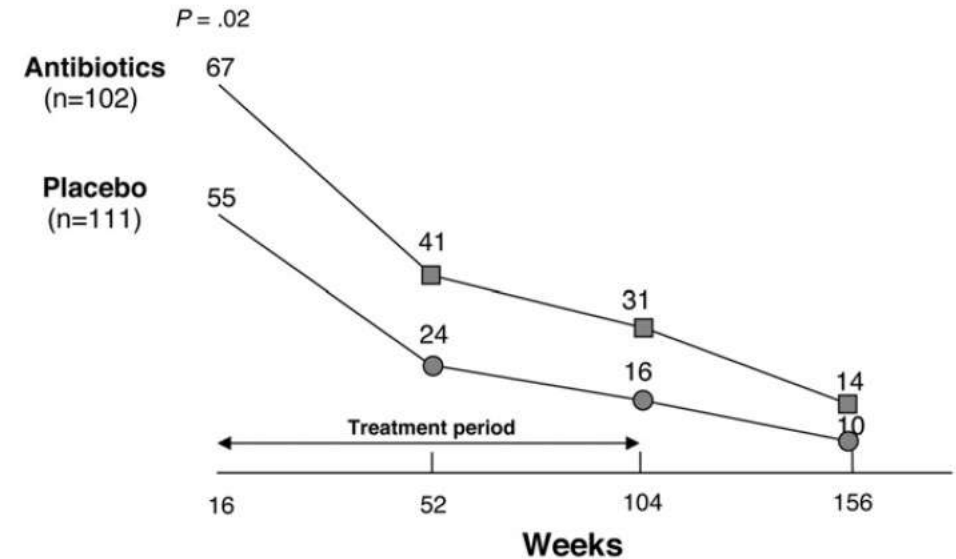


Figure 2. Subjects remaining in remission at each time point.

