

Clinical and endosonographic effect of ciprofloxacin on the treatment of perianal fistulae in Crohn's disease with infliximab: a double-blind placebo-controlled study

Double-blind, placebo-controlled, randomized trial. Adult patients with active perianal Crohn's disease (PCDAI >5) were randomized to ciprofloxacin 500mg BD or placebo for 12 weeks. All patients received 5mg/kg infliximab IV at weeks 6,8 and 12 and then q8w (Randomization stratified according to combo with AZA/MTX)

Primary endpoint: Clinical response $\geq 50\%$ reduction from baseline in the number of draining fistulae at week 18

Results: N=24

- At week 18 response 73% CIPRO-IFX vs 39% PLACEBO-IFX, $p=0.12$
- Logistic regression analysis showed patients treated with CIPRO-IFX tended to respond better OR 2.37 (95%CI 0.94-5.98), $p=0.07$.
- Perianal disease activity index score only improved in the CIPRO-IFX group, $p=0.008$

Conclusion:

A combination of ciprofloxacin and infliximab tended to be more effective than infliximab alone.

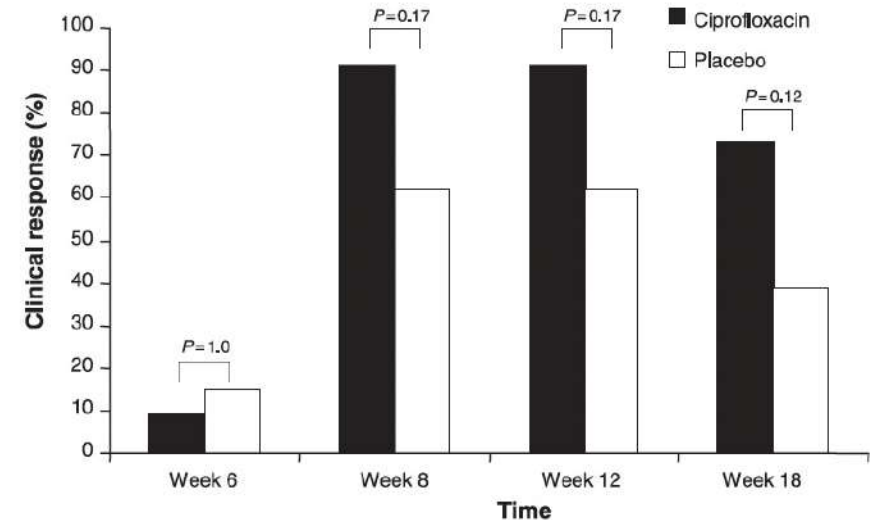


Figure 1. Clinical response at week 6, 8, 12 and 18 in the ciprofloxacin and placebo group.

