

Randomized, double-blind, placebo-controlled induction trial of rectal tacrolimus in patients with active ulcerative proctitis. Patients were randomized to rectal tacrolimus (0.5 mg/mL) or placebo, for 8 weeks.

Primary endpoints: Clinical response by Mayo Clinic score

#### Results:

- Clinical response at week 8, Tacro 73% vs placebo 10%;  $p=0.004$
- Clinical remission at week 8: Tacro 45% vs placebo 0%;  $p=0.015$
- Mucosal healing at week 8: Tacro 75% vs 10% placebo,  $p=0.004$

#### Conclusion:

Rectal tacrolimus was more effective than placebo for induction of a clinical response, clinical remission, and mucosal healing in resistant ulcerative proctitis

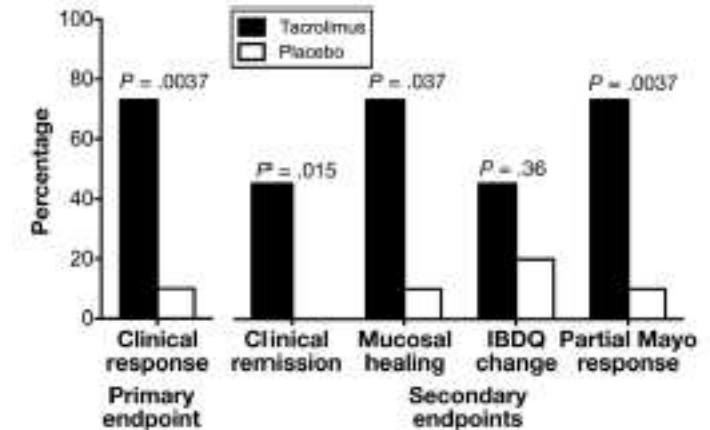


Figure 1. Primary and secondary endpoints at Week 8.