

Randomized, double-blind, placebo-controlled induction trial. Patients with active ulcerative colitis proctitis (maximum extension 25 cm) were randomized to rectal tacrolimus 0.5mg/mL vs placebo for 8 weeks. All patients had failed to 5ASA oral and/or topical and rectal steroids or were intolerant to these therapies.

Primary endpoints: Clinical response by Mayo Clinic score

*Study was closed because of ethical considerations after demonstrating highly significant differences between groups

Results: N=20

- Clinical response: 73% TACRO vs 10% placebo, $p=0.004$
- Clinical remission: 50% TACRO vs 0% placebo, $p=0.015$
- Mucosal healing at week 8: 73% TACRO vs 10% placebo, $p=0.004$
- There were no safety issues identified with rectal tacrolimus use.

Conclusion:

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

Efficacy of Rectal Tacrolimus for Induction Therapy in Patients With Resistant Ulcerative Proctitis

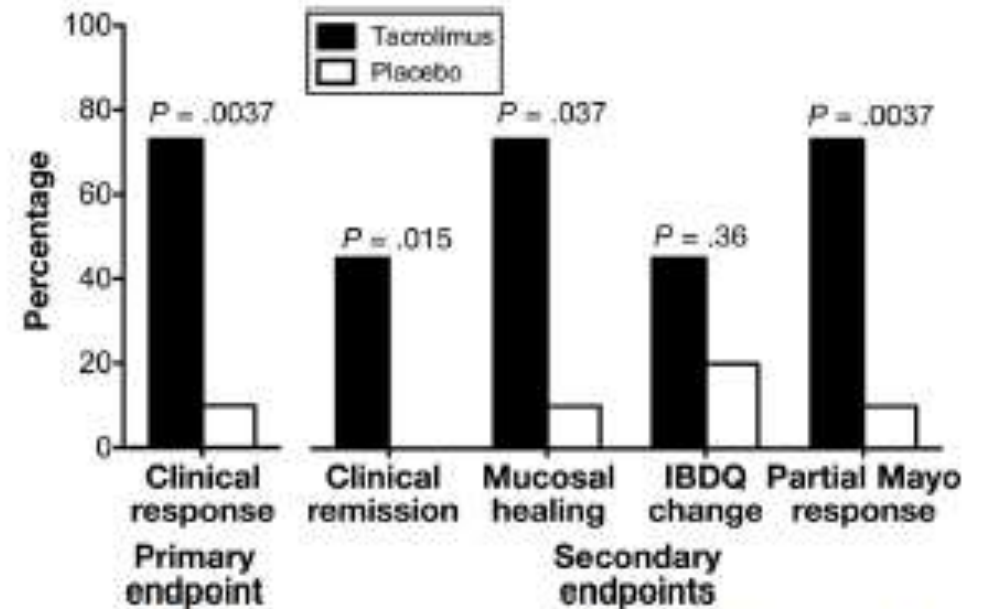


Figure 1. Primary and secondary endpoints at Week 8.

