

Phase III. Two identically designed, randomized, double-blind, placebo-controlled trials.
Mild to moderate UC proctitis/proctosigmoiditis patients were randomised to budesonide foam 2mg/25mL BD for 2 weeks, then OD for 4 weeks or placebo.
Concomitant use of mesalazine 4.8 gr orally per day was allowed.

Primary endpoints: Clinical remission at week 6

Results:

- Clinical remission at week 6: 41.2% budesonide foam vs 24% placebo, $p < 0.0001$
- Mayo rectal bleeding subscore 0 at week 6: 48.3% vs 28.3%, $p < 0.0001$

Conclusion:

Budesonide rectal foam was well tolerated and more efficacious than placebo in inducing remission in patients with mild to moderate ulcerative proctitis and ulcerative proctosigmoiditis.

Budesonide foam induces remission in patients with mild to Moderate UC proctitis and UC proctosigmoiditis

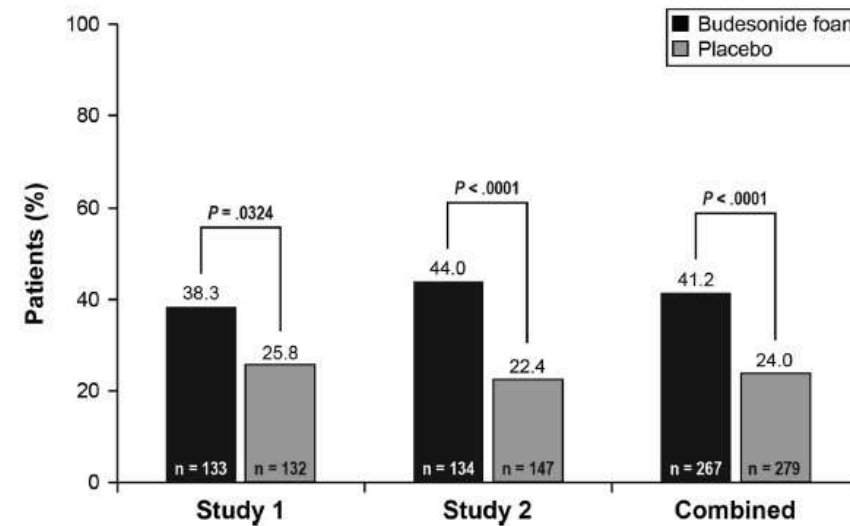


Figure 1. Patients achieving remission at week 6 (primary efficacy measure). Remission defined as endoscopy score ≤ 1 , rectal bleeding score = 0, and improvement or no change from baseline in stool frequency subscales of the Mayo score.

