

Double-blind, multicenter trial.

Patients with an acute flare of UC with baseline modified mayo score between 6-10 were randomized to receive balsalazide 6.6 gr per day or placebo

Primary endpoints: Clinical improvement at week 8.

Results:

- Clinical improvement at week 8: 55% balsalazide vs 40% placebo, $p=0.02$
- Clinical remission 38.6% vs 22.9% placebo, $p=0.0096$

Conclusion:

Balsalazide disodium 1.1 gr tablets at 3.3 g twice daily dose are effective, well tolerated and better than placebo for improving signs and symptoms of mild-to-moderately active UC.

Safety and Efficacy of a New 3.3 g b.i.d. Tablet Formulation in Patients With Mild-to-Moderately-Active Ulcerative Colitis: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study

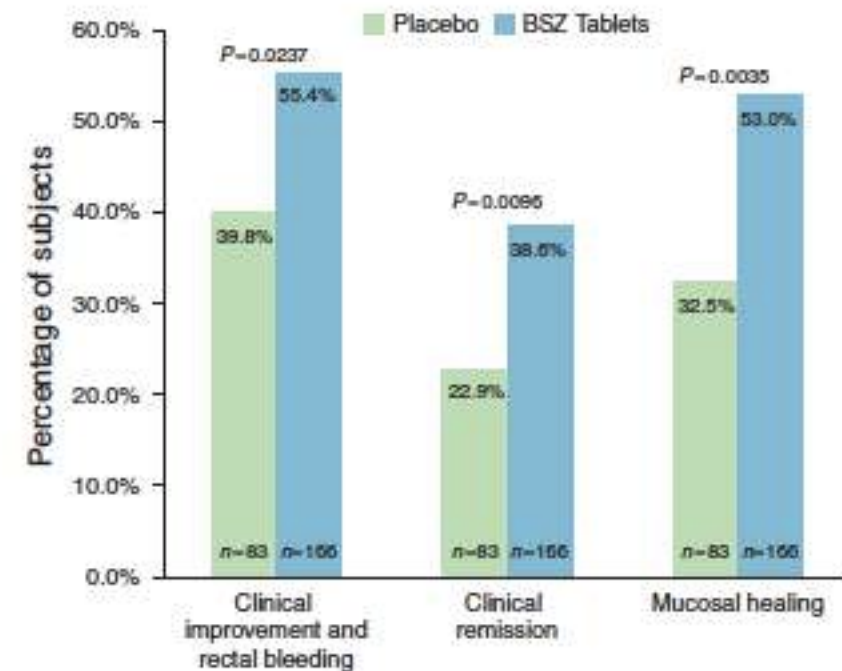


Figure 2. Percentage of patients by treatment group achieving clinical improvement, clinical remission, and mucosal healing.

