

3g mesalazine granules are superior to 9mg budesonide for Achieving remission in active ulcerative colitis: A double-blind, double-dummy, randomised trial

Randomised, double-blind, double-dummy, multicentre study. Patients with mild-moderate UC were randomised to 3g granule mesalazine vs 9mg budesonide (budenofalk 3 mg capsules) for 8 weeks

Primary endpoints: clinical remission at week 8 (CAI ≤ 4 with stool frequency and rectal bleeding subscores of "0").

Results:

- Clinical remission at week 8: 39.5% budesonide vs 54.8% 5ASA, $p=0.520$
- Median time to resolution of symptoms was 14 days in budesonide vs 11 in 5ASA
- Mucosal healing in 30.5% budesonide vs 39.2% mesalazine, $p=0.093$

Conclusion:

Once-daily 3 g mesalazine administered as granules is numerically superior to 9 mg budesonide OD administered as capsules for achieving remission in mild-to-moderately active UC. However, it is noteworthy that remission of UC was attained in about 40% of budesonide-treated patients with a rapid onset of resolution.

Table 2 Clinical remission at week 8 (LOCF) [ITT and PP populations].

	Clinical remission		Difference [95% CI]	P value ^a
	Budesonide	Mesalazine		
ITT population	70/177 (39.5%)	91/166 (54.8%)	-15.3% [-25.7%, -4.8%]	0.520
PP population	67/153 (43.8%)	89/149 (59.7%)	-15.9% [-27.1%, -4.8%]	0.566

^a Shifted asymptotic χ^2 -test for non-inferiority testing of budesonide vs. mesalazine (pre-specified non-inferiority margin -15%).

