

Randomised clinical trial: a comparative dose-finding study of three arms of dual release mesalazine for maintaining remission in ulcerative colitis

Multicentre, double-blind, double-dummy, 1 year trial. Patients with endoscopically and histologically confirmed UC in remission were randomized to oral mesalazine 3g OD, 1.5 g OD or 0.5g three times per day (TDS).

Primary endpoint: Clinical remission at 1 year

Results: N=647

- Clinical remission at 1 year was 75% 3gOD vs 61% 1.5gOD and 69% 0.5TID.
- Superiority testing showed higher rate of primary efficacy endpoint in the 3g group vs 1.5g and vs 0.5gTID

Conclusion:

Mesalazine 3.0 g once daily was the most effective dose for maintenance of remission in ulcerative colitis of the three regimens assessed, with no penalty in terms of safety.

