2013. MOTUS

RCT/ 5ASA/UC/ Remission

Randomised clinical trial: once- vs. twice-daily prolonged release mesalazine for active ulcerative colitis

Phase IIIb, randomised, controlled, investigator-blinded trial.
Mild-moderate UC patients were randomised to:

- 8weeks of mesalazine 4g/day either OD with 2 sachets of 2 gr in the morning or
- BD with one 2 g sachet in the morning & one in the evening.

Primary endpoint: non-inferiority 5ASA 4gr OD vs 2 gr BD at 8 weeks
Secondary endpoints: Improvement of UC-DAI score; mucosal healing; time to remission and safety.

Results:

- w8 endoscopic remission: 52.1% OD vs 41.8% BD; p=ns
- UC-DAI score improvement: 82% OD vs 79% BD; p=0.01
- Mucosal healing: 87.5% OD vs 71.1% BD; p=0.007
- Time to remission: 26 OD vs 28 days BD: p=0.04

Conclusions:
Prolonged-release mesalazine once-daily 4 gr is as effective and well tolerated as 2 gr twice-daily for inducing remission in patients with mild-to-moderately active UC.

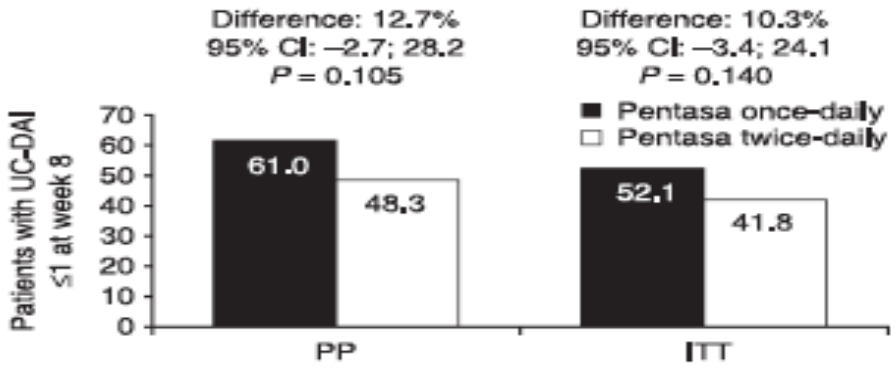

Figure 2 | Clinical and endoscopic remission rates at week 8. Percentage of patients achieving remission (UC-DAI ≤ 1) in the ITT and PP populations for OD vs. BD prolonged-released mesalazine treatment for mild-to-moderate UC. BD, twice-daily; CI, confidence interval; DAI, disease activity index; ITT, intent-to-treat; OD, once-daily; PP, per-protocol; UC, ulcerative colitis.

Flourié B et al. Aliment Pharmacol Ther 2013; 37:767-775