

Multicenter, randomized, double-blind placebo controlled. Patients with active UC with PUCAI of 10-55 points were randomized in blocks of six with blinded allocation to OD or BD mesalazine using a weight-based dosing table.

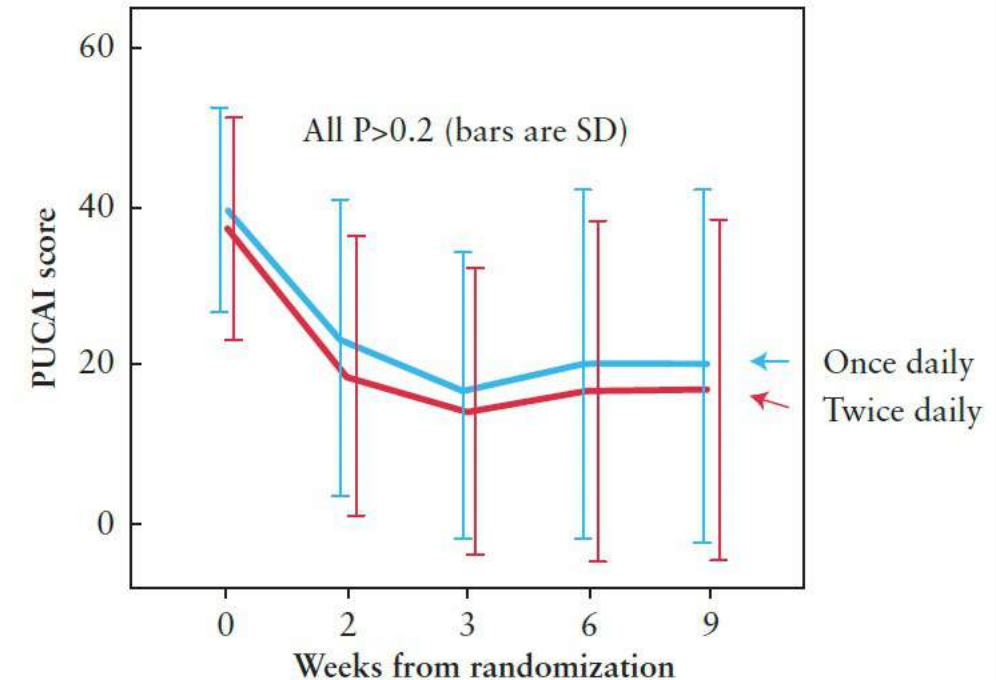
Primary endpoint: Mean PUCAI score at w6

Results: N=83

- No differences in median PUCAI in the OD and BD group at week 6, 15 vs 10 p=.48
- No differences in clinical response 60% vs 63%, p=0.78
- Clinical remission (PUCAI<10) at w6 was 30% OD vs 40% BD, p=0.35

Conclusion:

In this first randomised controlled trial in children, no differences were found between OD and BD dosing for any clinical outcome. Remission was achieved in 35% of children treated with mesalazine for active UC.



**Figure 2.** Paediatric Ulcerative Colitis Activity Index [PUCAI] scores in all study visits (last observation carried forward [LOCF] imputation).