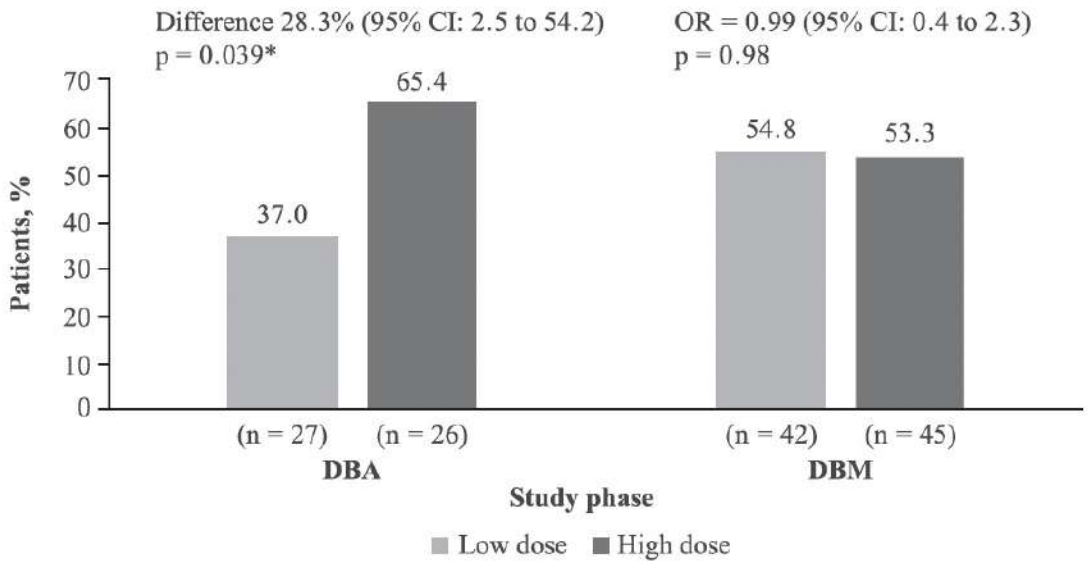
2023. Mesalazine MMX kids

RCT/5ASA/UC pediatric/ Induction

Safety and efficacy of multimatrix mesalamine in paediatric patients with mild-to-moderate ulcerative colitis: a phase 3, randomised, double-blind study

Prospective, randomised, parallel-group, phase 3 study (8w double-blind acute [DBA] phase; 26w double-blind maintenance [DBM] phase; and an additional 8-week, open-label acute [OLA].
Patients aged 5–17 were randomised 1:1 to either low (900–2400 mg) or high (1800–4800 mg) oral doses of multimatrix mesalamine once daily, stratified by body weight.

Primary endpoints: Clinical response of multimatrix mesalamine (two doses) in different weight groups.



Results: N=107

- Induction: High-dose group (n = 17; 65.4%) achieved a higher clinical response rate than the low-dose (n = 10; 37.0%) group; odds ratio (OR) 3.21 (95% CI: 1.04–9.88).
- At W26, similar proportions of patients maintained clinical response in the low-dose (n = 23; 54.8%) & high-dose (n = 24; 53.3%) groups: OR 0.99 (0.42–2.34); p = 0.981.
- Treatment-emergent adverse events were 23 TEAEs in 14 patients (13.3%) considered related to the study drug.

Conclusion:
Findings suggested that the benefit-risk ratio of once-daily MMX mesalamine in paediatric patients was favourable and comparable with that reported in adults with mild-to-moderate UC.

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