

1980. 5ASA/ Sulphapyridine

RCT/5ASA-Sulphapyridine/proctitis/Induction

Effect of sulphapyridine, 5-aminosalicylic acid, and placebo in patients with idiopathic proctitis: a study to determine the active therapeutic moiety of sulphasalazine

Randomized double-blind controlled trial.
Patients with active ulcerative colitis (proctitis) were randomized to receive suppositories twice daily of 5ASA 200mg /day vs Sulphapyridine (SP) 300mg/day vs placebo.
Patients were excluded if they received any therapy within the previous month.

Primary endpoints: Clinical remission at week 4

Results: N=45 (21 of which were included twice in the trial)

- Clinical remission at week 4: 5ASA 60% vs 13% SP vs 26.7% placebo. $p=0.02$ for the difference between 5ASA and SP
- Endoscopic remission at week 4: 5ASA 60% vs 13% SP vs 26.7% placebo. $p=0.02$ for the difference between 5ASA and SP

Conclusion:

The results suggest that 5ASA is the therapeutically active moiety of salicylazosulphapyridine. SP was not more effective than placebo and it was inferior to 5ASA in treating UC proctitis

Table 2 *Clinical progress after treatment for four weeks*

	Type of suppository		
	5-ASA (n=15)	SP (n=15)	Placebo (n=15)
No symptoms	9	2	4
Improved	1	1	0
Unchanged	4	9	7
Worse	1	3	4

Table 3 *Sigmoidoscopic appearance after treatment for four weeks*

	Type of suppository		
	5-ASA (n=15)	SP (n=15)	Placebo (n=15)
Normal	9	2	4
Improved	2	2	1
Unchanged	4	9	8
Worse	0	2	2

Table 4 *Results of treatment with 5-ASA, SP, and placebo*

Type of suppository	Patients (no.)	Patients in remission		Significance of differences
		(no.)	(%)	
5-ASA	15	9	60	} $P=0.020$
SP	15	2	13.3	
Placebo	15	4	26.7	

$\chi^2=7.8$; DF=2.

