

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 5ASA (200mg x2), sulphapyridine (300mg x 2) or placebo suppositories twice daily.

Primary endpoints: Clinical remission and normal endoscopy at 4 weeks.

Results: N=45

- Clinical remission with normal sigmoidoscopy: 60% 5ASA vs 13% sulphapyridine and 27% placebo, $p=0.020$
- Clinical remission or improvement 66.7% 5ASA vs 20% sulphapyridine vs 26.7% pbo.
- Difference between 5ASA and Sulphapyridine, $p=0.021$

Conclusion:

The results suggest that 5ASA is the active therapeutic moiety of sulphasalazine.

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.

