

Randomized double-blind trial.

Patients with mild-moderate active ulcerative colitis (left sided). First part were randomized to receive 1gr of 4ASA enema vs placebo. Second part randomized to 2gr 4ASA vs placebo. One enema per night for 2 weeks.

No steroids allowed at entry of the study oral sulphasalazine allowed.

Primary endpoints: clinical response at week 2 and endoscopy.

Results: N=52

- Clinical response: 4ASA-1gr 73.3% vs 33.3% placebo, $p < 0.005$
- Clinical response: 4ASA-2gr 90% vs 50% placebo, $p < 0.005$
- Endoscopic improvement w2: 66.7% 4ASA-1gr vs 33.3% placebo, $p < 0.05$
- Endoscopic improvement: 4ASA-2gr 80% vs 33.3% placebo, $p < 0.005$

Conclusion:

These findings suggest that 4-ASA may provide a stable, inexpensive alternative to 5-ASA for the topical treatment of ulcerative colitis or for linking to carrier molecules for release in the colon.

Table I. Clinical response to 4-ASA or placebo enemas

	Improved n	Unchanged or worse n	Total n
1-gram regimen			
4-ASA	11	4	15
Placebo	5	10	15
2-gram regimen			
4-ASA	9	1	10
Placebo	6	6	12

Cochran's test: $\chi^2 = 8.81$; $p < 0.005$.

Table II. Sigmoidoscopic response

	Improved n	Unchanged or worse n	Total n
1-gram regimen			
4-ASA	10	5	15
Placebo	4	11	15
2-gram regimen			
4-ASA	8	2	10
Placebo	4	8	12

Cochran's test: $\chi^2 = 9.56$; $p < 0.005$.

