

Randomized, single center, placebo-controlled trial. Patients with mild-to-moderate left-sided UC received daily enemas of 5 µg of EGF in 100 ml of an inert carrier and 12 received daily enemas with carrier alone for 14 days.

All patients received 1.2 gr oral mesalazine per day.

Primary endpoints: Disease remission at week 2.

Results:

- Clinical remission week 2: 83%EGF vs 8% placebo, $p < 0.0001$
- At 2 weeks, disease activity scores, sigmoidoscopy score, histological scores were all significantly better in EGF than placebo, $p < 0.01$ for all comparisons.

Conclusion:

The effectiveness of mesalazine suppositories in all types of UC patients with rectal inflammation was confirmed for the first time in a double-blind, placebo-controlled, parallel-group study

Epidermal Growth Factor Enemas with Oral Mesalamine for Mild-to-Moderate Left-Sided Ulcerative Colitis or Proctitis

Table 2. Changes in Disease Activity among Patients Who Received Epidermal Growth Factor (EGF) or Placebo Enemas for 14 Days in Addition to Mesalamine.

Variable	Before Treatment	At 2 Weeks	At 4 Weeks*
	<i>median (interquartile range)</i>		
St. Marks score [†]			
EGF	10 (8.75–10.25)	3 (2–4.25) [‡]	2 (1–3) [‡]
Placebo	9 (9–10)	8.5 (6–11)	6.5 (3–8.75)
P value	0.74	0.005	0.04
Simplified symptom score [§]			
EGF	2.5 (2–3)	0 (0–0.75) [‡]	0 (0–0) [‡]
Placebo	2 (2–2)	2 (1–2.75)	1.5 (0.25–2.75)
P value	0.26	0.002	0.02
Sigmoidoscopic score			
EGF	3 (2–3)	1 (1–1) [‡]	1 (0–1.75) [‡]
Placebo	2.5 (2–3)	2 (2–3)	2 (1–3)
P value	0.51	<0.001	0.04
Histologic score [¶]			
EGF	3 (3–3)	2 (1–2) [‡]	1 (1–2) [‡]
Placebo	3 (2–3)	3 (2–3)	2.5 (1.75–3)
P value	0.26	0.002	0.05

* Data were missing for two patients in the placebo group who were withdrawn from the study at two weeks because of worsening symptoms.

[†] A score of 4 or less represented remission, with no inflammation on sigmoidoscopy.

[‡] $P < 0.01$ for the comparison with the value before treatment.

[§] A score of 0 represented remission, with no visible blood in stool.

[¶] No dysplasia was observed in any biopsy specimen at any time.

