

Randomised double-blind, parallel group, placebo controlled, 8week.
Patients with mild-moderate extensive UC.

Group I: 5ASA 4gr oral + enema (1gr 5ASA)

Group II: 5ASA 4gr + enema placebo

Primary end point: remission at w4 based on UCDAI

Secondary: Remission at w8; Improvement rates at w4 & w8; Time to cessation of rectal bleeding.

Results:

- Remission w4: 44% vs 34% (pbo enema); p=ns
- Remission w8: 64% vs 43% (pbo enema); p=0.03
- Improvement w4: 89% vs 62% (pbo enema); p=0.0008

Conclusions:

In extensive mild-moderate active UC, enema + oral mesalazine is superior than oral alone.

Combined oral & enema treatment with Pentasa (mesalazine) is superior to oral therapy alone in patients with extensive mild-Moderate UC: a randomised, double blind, placebo controlled study

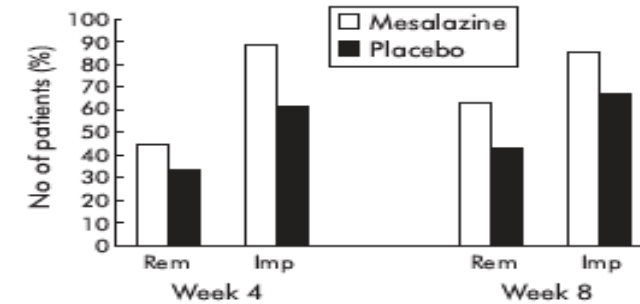


Figure 2 Remission and improvement rates. Percentage of patients achieving remission (ulcerative colitis disease activity index (UCDAI) of 0 or 1) or improvement (decrease in UCDAI > 2 points). Rem, remission; Imp, improvement.

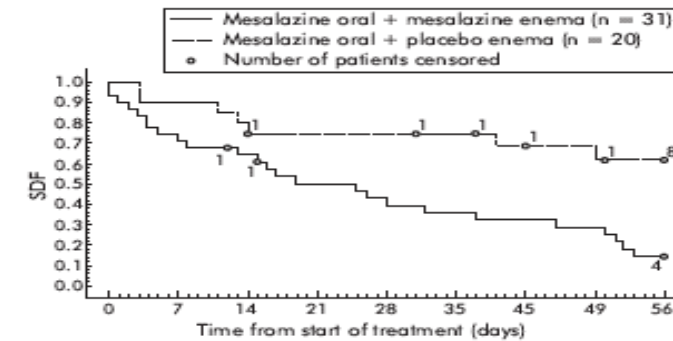


Figure 3 Time to cessation of rectal bleeding in patients with frank bleeding at baseline. SDF, survival distribution function from Kaplan-Meier survival analysis (proportion of patients with rectal bleeding). All patients without cessation of rectal bleeding by day 56 or who withdrew prematurely were censored.

