RCT/Mesalazine supp/UC /Induction

Randomised clinical trial: evaluation of the efficacy of mesalazine (mesalamine) suppositories in patients with UC and active rectal inflammation – a placebocontrolled study

Phase III. Multicenter randomized, double-blind parallel-group trial. Mild-Moderate UC patients with rectal inflammation were randomized to: 1gr/day mesalazine suppository or placebo for 4 weeks.

Primary endpoints: Endoscopic remission (Mayo score 0-1)

Results:

- Endoscopic remission rates at week 4: 81.5% mesalazine suppositories vs 29.7%pbo, p<0.0001.
- Endoscopic remission in proctitis 83.3%, 78.6% in left side UC and 21.4% in extensive colitis, p<0.0001 for both groups.
- Clinical remission at week 4: 63.1% mesalazine supp vs 17.2% pbo, p<0.0001

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

Table 3 | Endoscopic remission and clinical remission after 4 weeks of treatment

	Mesalazine suppositories *N* (%)	Placebo suppositories *N* (%)	Between-group difference (%) [95% confidence interval]	*P*-value‡
Endoscopic remission*	53/65 (81.5)	19/64 (29.7)	51.9 [37.2, 66.5]	$P < 0.0001$
Clinical remission†	41/65 (63.1)	11/64 (17.2)	45.9 [31.0, 60.8]	$P < 0.0001$

* Patients with mucosal score of 0 or 1 after 4 weeks of treatment (or at time of discontinuation).
† Patients with UC-DAI of 2 or less and bleeding score of 0 after 4 weeks of treatment (or at time of discontinuation).
‡ Two-tailed level of significance 5% (χ^2-test).

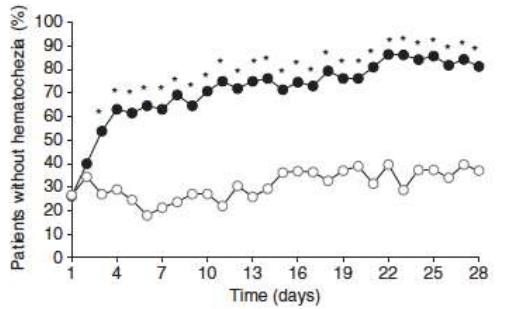

Figure 2 | Percentage of patients without bleeding, based on patient diaries. Mesalazine suppositories (●, $N = 65$), placebo suppositories (○, $N = 64$). * A statistically significant difference ($P < 0.0005$) was found between mesalazine suppositories and placebo (Fisher's exact test, two-tailed level of significance 5%).

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