4-week, placebo-controlled, double-blind trial.

Patients with extensive or left side mild to moderate UC were randomized to 5ASA 3.2g/d plus oral beclomethasone (BDP) 5mg/day or placebo+5ASA.

Primary endpoint: Clinical remission week 4.

Results: N=119

- At week 4, disease activity index was lower in BDP+5ASA vs 5ASA+placebo, p=0.014.
- Clinical remission at w4: 58.6% vs 34.4%, p=0.008.
- Low incidence of adverse events was observed in both groups.

Conclusion:

Oral BDP in combination with oral 5ASA is significantly more effective than 5ASA alone in the treatment of patients with extensive or left-sided active ulcerative colitis.

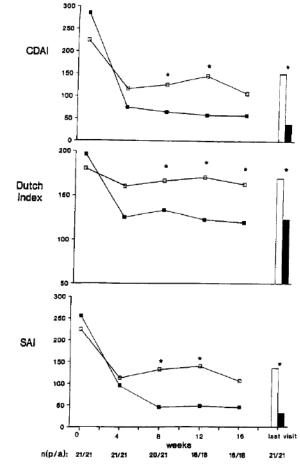


Figure 2. Median of activity indices month by month in the AZA- (a, ■) and placebo-treated (p, □) groups. n, no. of patients. *Last visit*, median of activity indices (regular term or insufficient treatment) for CDAI, ¹³ Dutch index, ¹⁴ and SAI. ¹⁵ *P < 0.05.

