

Double-blind, placebo-controlled, multicentre trial. Patients with CD who achieved remission previously on budesonide 9mg/day were randomly assigned to budesonide 6 mg/day or placebo for 52 weeks.

Primary endpoints: Time to relapse (CDAI>150) plus an increase of at least 60 points from study entry..

Results: N=110

- Time to relapse was 260 days for budesonide patients vs 169 days for placebo, p=0.132
- Budesonide was safe and well tolerated with a similar adverse event profile to placebo

Conclusion:

Patients treated with budesonide 6 mg once daily had a trend towards a prolonged time to relapse and lower CDAI scores compared with patients treated with placebo, but relapse rates were not significantly different at the 1-year end point.

**Budesonide as maintenance treatment in Crohn's disease:  
a placebo-controlled trial**

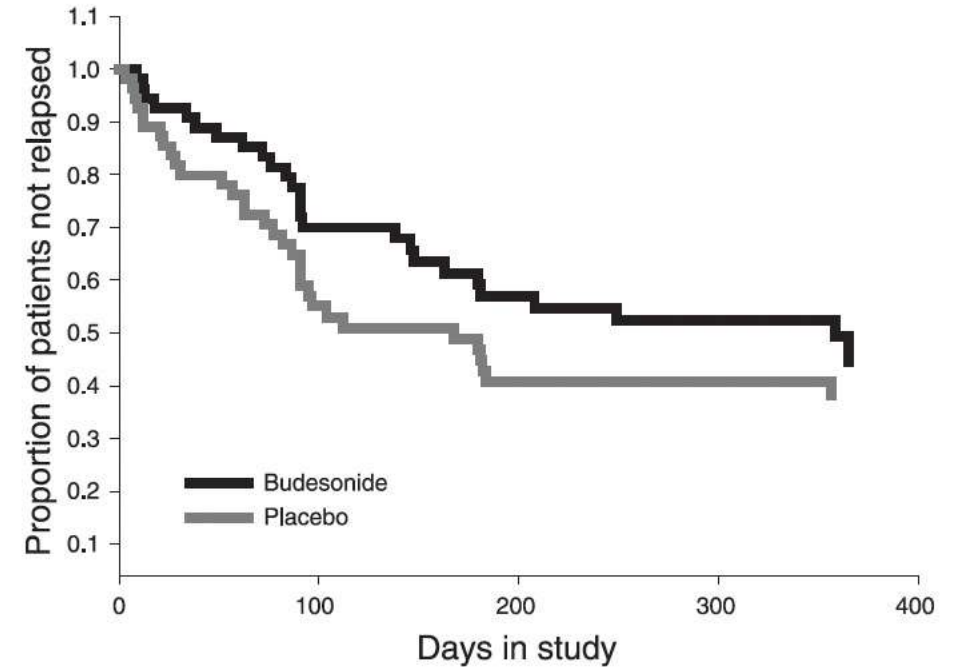


Figure 2. Kaplan–Meier estimates for proportion of patients not relapsed over time. At day 0, 90, 180, 270, and 360, the number of patients not relapsed were 55, 41, 28, 24, and 16, respectively, for those treated with budesonide 6 mg once daily and 55, 34, 24, 19, and 13, respectively, for those treated with placebo.

