

Randomized, double-blind, double-dummy, controlled trial. Patients age 6-16 years old with active CD were randomized to:
-Budesonide (9mg/day for 8 weeks, 6 mg/day for 4 w) or prednisolone (1mg/kg/d for 4 weeks, tapering for 8 weeks)

Primary endpoint: CDAI remission at 8 weeks

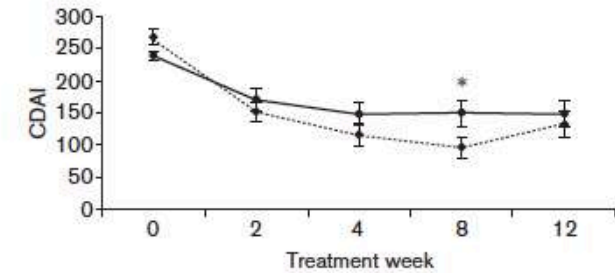
Results:

- Remission at 8w, 55% budesonide vs 71% prednisone, $p=0.25$.
- Mean morning plasma cortisol after 8 weeks higher in the budesonide group than prednisone, 300nmol/L vs 98nmol/L, reflecting less adrenal suppression with budesonide, $p=0.0028$

Conclusions:

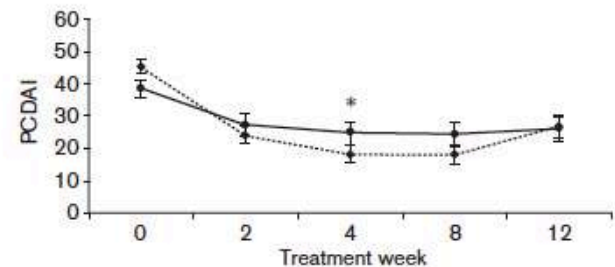
Significantly fewer side effects and less adrenal suppression were observed in the children receiving budesonide. Remission rates were not significantly different in the two groups. However, there was a trend for prednisolone to be more effective for inducing remission.

Fig. 4



Mean (\pm SE) scores on the Crohn's Disease Activity Index (CDAI) at baseline and during treatment with budesonide or prednisolone. At week 8, the difference between the treatment groups was statistically significant (* $P = 0.047$). (---), prednisolone; (—), budesonide.

Fig. 5



Mean (\pm SE) scores on the Paediatric Crohn's Disease Activity Index (PCDAI) at baseline and during treatment with budesonide or prednisolone. At week 4, the difference between the treatment groups was statistically significant (* $P = 0.034$). (---), prednisolone; (—), budesonide.

