2014. Budesonide dose

RCT/Budesonide/ CD/ Induction

Once versus three times daily dosing of oral budesonide for active Crohn's disease: A double-blind, double-dummy, randomised trial

Multicentre, double-blind, double-dummy, phase III trial.
Patients with mild-moderately active ileocolonic CD (CDAI >200-<400) were randomized to 9mg budesónida OD or 3mg three-times daily (TID).

Primary endpoint: Clinical remission defined as CDAI <150 at week 8 (last observation carried forward)

Results: N=471

- At week 8: 71.3% 9mg budesonide vs 75.1% 3mg TID, a difference of -3.9% p=0.020 for non-inferiority.
- Mean time to remission was 21.9 days vs 21.4 days in 9 mg vs 3 mg TID.
- No differences in adverse events

Conclusion:
Budesonide at the recommended dose of 9 mg/day can be administered OD without impaired efficacy and safety compared to 3 mg TID dosing in mild-to-moderately active Crohn's disease.

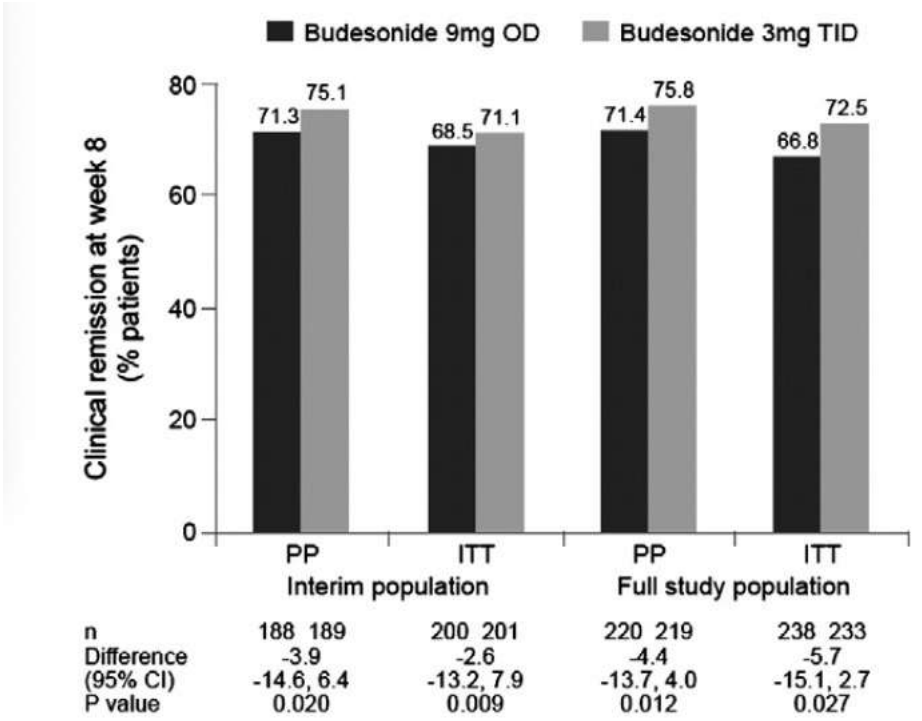

Figure 2 Clinical remission at week 8 (LOCF). Results are shown for the interim population (confirmative analysis) and the full study population (explorative analysis).

Dignass A et al. J Crohns Colitis. 2014; 8: 970-980