OC-074

ONCE DAILY ASACOL® IN MAINTENANCE THERAPY FOR ULCERATIVE COLITIS: A ONE-YEAR SINGE-BLIND RANDOMISED TRIAL

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Introduction Mesalazine has traditionally been administered in divided doses, but there is emerging evidence that once daily dosing is no less effective and may improve treatment adherence.

Methods The Colitis Once Daily Asacol® (CODA) study was designed to assess the efficacy and safety of once daily dosing with Asacol® 2.4 g given as 3 × 800 mg tablets (OD) in comparison with three times daily dosing (one 800 mg tablet three times daily) (TDS). Adult UC patients taking mesalazine or sulphasalazine in remission for >4 weeks and <2 years were randomised (investigator-blind) to OD or TDS dosing. The primary end-point was the difference between groups in relapse rates over one year. Relapse was defined as typical symptoms of relapse with a Baron sigmoidoscopy score of 2 or 3. With estimated relapse rate of 20–30%, and a meaningful difference of 10% between groups, 250 patients were required to demonstrate non-inferiority with one-sided α of 5% and 1-β of 80%. Non-inferiority would be concluded if the upper limit of the 95% confidence interval (CI) for the difference between treatments was <10% for both per protocol (PP) and intention to treat (ITT) population. (For ITT analysis, missing data was imputed as relapse.)

Results 213 patients were recruited in 32 UK centres. Groups were well matched. There was no difference in adverse events between OD and TDS groups. Primary analysis confirmed non-inferiority of once-daily dosing. In a secondary analysis, (table 1) both ITT and per protocol (PP) populations demonstrated superiority of OD versus TDS dosing which was statistically significant. A multivariable analysis of baseline factors

Table 1 OC-074 Relapse rate at 1 year

	OD (n = 103)	TDS (n = 110)	Difference
No. of relapses	23	33	
Relapse rate (95% CI) ITT population	31% (22–40%)]	45% (35–54%)	-13% (-26 to -1%)
Relapse rate [95% CI] PP population	20% (11–28%)	35% (24–45%)	-15% (-29 to -2%)

predicting relapse will be presented. Self-reported adherence at 12 months or relapse was >90% in 97% of patients (OD group) and 85% (TDS group). When asked how easy it was to remember to take tablets, it was reported to be very or fairly easy in 98% (OD group) versus 73% (TDS group).

Conclusion Once daily dosing with Asacol™ 2.4 g is as safe and effective as three times daily dosing, and secondary analysis confirmed significantly reduced relapse rates. The benefit was, however, clinically borderline and may relate to ease of adherence.

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