

Two mesalazine regimens in the prevention of the post-operative recurrence of Crohn's disease: a pragmatic, double-blind, randomized controlled trial

Double-blind, randomized, multi-centre, prospective, controlled trial.

Patients with Crohn's disease undergoing their first or second surgery were randomised to mesalazine 4gr/day or 2.4gr/day started 2 weeks after surgery.

Primary endpoints: Endoscopic recurrence at 12 months (Rutgeerts >0, >1 or >2).

Results:

- Endoscopic recurrence at 12 months 46% (4gr) vs 62% (2.4gr), p=0.04
- No differences in endoscopic recurrence of >1 or >2 of Rutgeerts, p=0.19 and p=0.18 respectively.
- No differences in clinical recurrence 12% vs 14%, p=0.58

Conclusion:

A 4.0 g/day regimen of mesalazine does not offer a clinically significant advantage over a 2.4 g/day regimen in the prevention of post-operative endoscopic and clinical recurrence of Crohn's disease at 1 year of follow-up.

Table 2. Endoscopic recurrence at 1 year of follow-up

Endoscopic score	4.0 g/day	2.4 g/day	P
> 0 (1-4)	39 (46%)	50 (62%)	0.04
> 1 (2-4)	28 (33%)	35 (43%)	N.S.
> 2 (3-4)	23 (27%)	30 (37%)	N.S.

