1980. Mercaptopurine

RCT/Mercaptopurine/CD/ Induction

Treatment of Crohn's disease with 6-Mercaptopurine: A Long-term, Randomized, Double-Blind Study

Randomized double blind crossover 2-year study.
Patients with active Crohn's disease who failed to steroids and sulfasalazine were randomized to 6-Mercaptopurin (6-MP) 1.5mg/kg/day and placebo for a year with a crossover design. Conventional therapy was prescribed for all patients with neither sulfasalazine nor steroids being withdrawn on entry into the study.

Primary endpoints: Clinical remission, reduction of steroid dose and fistula healing at 3 months intervals

Results: N=83 (n=39 crossed over)

- Crossover group: Improvement during a year on 6-MP 67% vs 8% pbo, p<0.0001.
- No crossover:n= 33, improvement 79% 6-MP vs 29% pbo, p<0.05
- Combined results of crossover & non crossover 72% 6-MP vs 14% pbo, p<0.0001
- Fistula closure 31% 6MP vs 6% pbo.
- Steroid discontinuation or reduction occurred in 75% 6MP vs 36% pbo, p<0.0001
- Mean time of response in te patients on 6MP was 3.1 months

Conclusion:
Mercaptopurine was better than placebo inducing clinical remission, reduction of steroids dosage and fistula healing.

Table 2. Results in 39 Crossover Patients.

Treatment	Improved *	Not Improved
	Number of Patients	
6-MP	26/39	13/39
Placebo	3/39	36/39

*Whereas 67 per cent of patients improved with 6-MP, only 8 per cent improved with placebo. The difference is 59 per cent with 95 per cent confidence limits of 32 to 86 per cent (P<0.0001).

Table 3. Results in 33 Non-Crossover Patients.

Treatment	Improved *	Not Improved
	Number of Patients	
6-MP	15/19	4/19
Placebo	4/14	10/14

*Whereas 79 per cent of patients improved with 6-MP, only 29 per cent improved with placebo. The difference is 50 per cent with 95 per cent confidence limits of 20 to 80 per cent (P<0.05).

Table 4. Combined Results during First Year.

Treatment	Improved *	Not Improved
	Number of Patients	
6-MP	26/36	10/36
Placebo	5/36	31/36

*Whereas 72 per cent of patients improved with 6-MP, only 14 per cent improved with placebo. The difference is 58 per cent with 95 per cent confidence limits of 40 to 77 per cent (P<0.001).

Present DH et al. N Engl J Med. 1980. 302(18):981-987