1991. METRO

RCT/ Metronidazole/ CD/Induction

Double blind, placebo controlled trial of metronidazole in Crohn's disease

Double blind, placebo-controlled multicentre trial.
Patients with Crohn's disease were randomized to metronidazole 20mg/kg, 10mg/Kg or placebo. All other medical therapy was stopped prior study entry.

Primary endpoints: Change in CDAI score measured at study entry and termination at week 16.

Results: N=105 (early closure of the trial)

- Only 56 patients completed the 16 weeks of study
- Significant improve was found in CDAI between the 3 groups, p=0.002
- No differences were found in CRP and remission between groups.

Conclusion:
Preliminary analysis suggests that metronidazole was more effective in patients with disease confined to the large intestine or affecting both small and large bowel than in those with small bowel disease only. There were no differences in remission rates between metronidazole and placebo treated patients. We conclude that metronidazole warrantsfurther a ssessment in the treatment of patients with active Crohn's disease

TABLE III *Changes in outcome measures (entry value−value at time of study completion or withdrawal) with 95% confidence intervals for all groups. A positive sign indicates improvement, while a negative sign indicates worsening disease. Significant differences in Crohn's disease activity index (CDAI) and orosomucoid value between metronidazole and placebo treated patients were detected*

	Metronidazole (10 mg/kg) (n=33)	*Metronidazole (20 mg/kg) (n=30)*	*Placebo (n=36)*	*p value*
CDAI	+67 (26–108)	+97 (55–139)	−1 (−37-45)	0·002
Orosomucoid	+38 (21–55)	+49 (20–70	−9 (−23–5)	0·001
C reactive protein	0·9 (−3·0–1·9)	0·8 (−1·0–2·7)	−0·9 (−1·9–0·1)	NS
Entering remission (%)	36	27	25	NS

Sutherland L et al. Gut. 1911; 32:1071-1075