

Phase 3, randomised, double-blind, placebo-controlled trial. Patients with active draining CD abdominal or perianal fistulas for the last 3 months were randomly assigned to infliximab 5mg/kg; 10mg/kg or placebo (0,2,6 weeks)

Primary endpoint: Reduction of 50% or more from base line in the number of draining fistulas observed at 2 or > consecutive visits

Results: N=94

- Reduction of 50% of draining: 68% IFX5 vs 56% IGX10 vs 26% placebo; p=0.002 and p=0.02.
- Fistula closure: 55% of IFX5 vs 38% IFX10 vs 13% placebo, p=0.001 and p=0.04.
- Median time during which fistulas remained closed was 3 months,

Conclusion:

Infliximab is an efficacious treatment for fistulas in patients with CD.

TABLE 2. OUTCOME OF TREATMENT, ACCORDING TO STUDY GROUP.

VARIABLE	PLACEBO	INFLIXIMAB		
		5 mg/kg	10 mg/kg	5 OR 10 mg/kg
End points				
Primary end point — no./total no. (%) [*]	8/31 (26)	21/31 (68)	18/32 (56)	39/63 (62)
P value vs. placebo	—	0.002	0.02	0.002
Complete response — no./total no. (%) [†]	4/31 (13)	17/31 (55)	12/32 (38)	29/63 (46)
P value vs. placebo	—	0.001	0.04	0.001
Time to onset of response (days) [‡]				
Median	42	14	14	14
Interquartile range	15–72	14–42	14–42	14–42
Duration of response (days) [‡]				
Median	86	84	99	86
Interquartile range	56–104	31–113	86–113	57–113

