

Open-label study, single center.

Patients with moderate-severe active Crohn's disease resistant to treatment received a single cA2 IV infusion at 10mg/Kg or 20mg/kg.

Primary endpoints: Safety and potential efficacy of cA2 (IFX). CDAI and endoscopy at week 4.

Results: N=10

- 8/10 patients had normal CDAI and healing of ulcerations in the colonoscopy at week 4.
- The average response after a single infusion was 4 months.
- Extra intestinal manifestations (arthralgia and pyoderma gangrenosum) if present improved after the infusion.

Conclusion:

Treatment with cA2 was safe and may be useful in patients with Crohn's disease who do not respond to steroids.

The cA2 monoclonal antibody= infliximab

Treatment of Crohn's disease with anti-tumor necrosis factor chimeric monoclonal antibody (cA2)

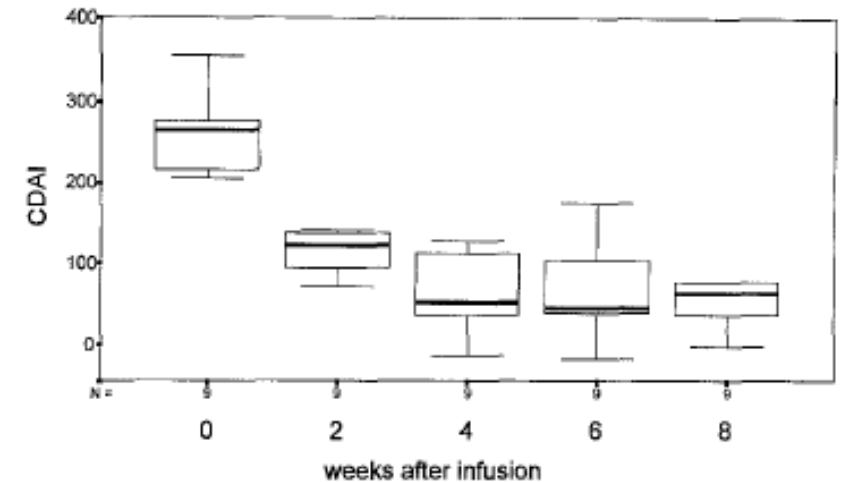


Figure 1. CDAI after infusion of cA2 (n = 9). Values represent means, bars represent the 25th and 75th percentiles, and error bars indicate the 5th and 95th percentiles ($P < 0.0001$).

