

Randomized double blind placebo-controlled multicenter trial. Patients with moderate-severe active Crohn's disease resistant to treatment were randomized to receive a single IV infusion of cA2 at 5mg/kg, 10mg/kg or 20mg/kg or placebo. Patients who did not have clinical response at week 4 entered an open-label study and received a single infusion of 10mg/Kg cA2. Steroids and thiopurines/methotrexate allowed.

Primary endpoints: Clinical response at week 4 (CDAI reduction of ≥ 70)

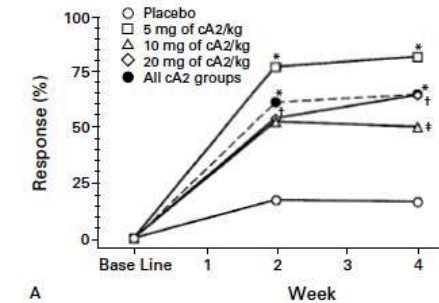
Results: N=108

- Clinical response at week 4: 81% (5mg) vs 50% (10mg) vs 64% (20mg) vs 17% placebo.
- Overall response to cA2 65% vs 17% placebo, $p < 0.001$
- Clinical remission at week 4: 33% cA2 vs 4% placebo, $p = 0.005$
- Clinical response at week 12: 41% cA2 vs 12% placebo, $p = 0.008$

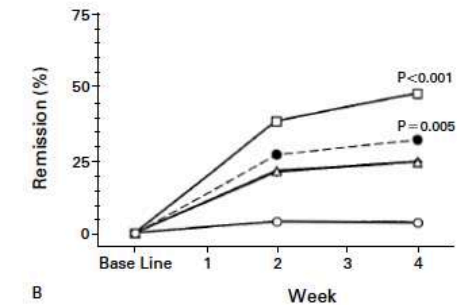
Conclusion:

A single infusion of cA2 was effective in the short-term in moderate-severe Crohn's disease.

The cA2 monoclonal antibody= infliximab



A



B

No. OF PATIENTS EVALUATED			
Placebo	25	24	24
5 mg of cA2/kg	27	26	27
10 mg of cA2/kg	28	23	28
20 mg of cA2/kg	28	28	28
All cA2 groups	83	77	83

Figure 1. Rates of Clinical Response and Remission after a Single Infusion of cA2 or Placebo. Clinical remission was defined as a score of less than 150 on the Crohn's Disease Activity Index and a score of 170 to 190 on the Inflammatory Bowel Disease Questionnaire. The asterisks ($P < 0.001$), daggers ($P < 0.01$), and double dagger ($P < 0.05$) indicate a significant difference from placebo.

