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CHRONOGRAPHY OF INFLAMMATORY BOWEL DISEASE

Year 1997: Short-term study of the cA2 chimeric monoclonal antibody directed against human tumour necrosis factor-alpha for Crohn's disease☆

Año 1997: estudio a corto plazo del anticuerpo monoclonal quimérico cA2 contra el factor de necrosis tumoral alfa para la enfermedad de Crohn

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And with cA2 (infliximab), biologics have reached IBD. In this induction study with a single dose of infliximab, its unequivocal efficacy was demonstrated in a high percentage of patients with moderate–severe Crohn's disease who had not responded to conventional treatment. Today this study, which defined previous failure on mesalazine as an inclusion criterion, and wherein the only objective variable to measure inflammation was serum C-reactive protein, would have serious difficulties not being rejected by a multitude of prestigious medical journals. But it was another time (pre-*mucosal healing*, pre-*histological healing*, etc.) and the drug showed an efficacy that was unmatched in treatments previously approved for Crohn's disease. What's more, of the 3 doses assessed, it seemed that the 5 mg/kg dose was even more effective than the 10 or 20 mg/kg dose, with the former being the dose that we continue to use 23 years later in all our patients with Crohn's disease. Later came trials with maintenance doses, and those done in patients with perianal Crohn's disease. The magnificence of this drug, which has helped so many people over more than 20 years, is that it continues to be the drug of choice for our patients with IBD, and there are already a multitude of biosimilars on the market. Any new biologic that wants to become part of the therapeutic arsenal for managing patients with IBD must take into account that infliximab obtained results in trials that are hard to beat, and continues to show them in our daily use, at least as far as efficacy is concerned. This drug still has, and will have, a lot to say in the coming years for managing our patients' conditions.

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A short-term study of chimeric monoclonal antibody cA2 to tumor necrosis factor alpha for Crohn's disease. Crohn's Disease cA2 Study Group

Targan SR, Hanauer SB, Van Deventer SJ, Mayer L, Present DH, Braakman T, et al. N Engl J Med. 1997;337:1029-35

1997: Short-term study of the cA2 chimeric monoclonal antibody directed against human tumour necrosis factor-alpha for Crohn's disease

Background

Various studies and trials suggested the role of the cA2 chimeric monoclonal antibody in the treatment of Crohn's disease.

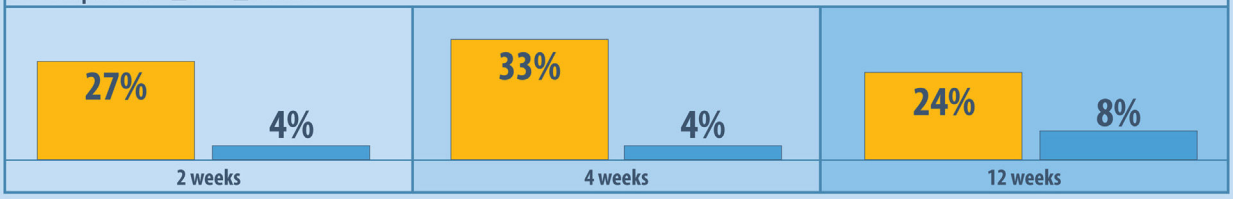
What was done?

Duration
21 June 1995 to
12 March 1996.

Clinical trial of cA2
12 week, multicentre,
double-blind,
placebo-controlled.

203 initial patients
95 excluded.
108 treated.

Clinical remission[α]



Clinical remission information. The drug is far superior to placebo, but leaves many patients having not achieved remission and, therefore, should be improved.

Clinical response[β]

N = 108 patients	cA2 5 mg/kg (N = 27)	cA2 10 mg/kg (N = 28)	cA2 20 mg/kg (N = 28)	Placebo (N = 25)
4 weeks	81% (22 of 27)	50% (14 of 28)	64% (18 of 28)	17% (4 of 24)
12 weeks	48%	29%	46%	

[α] Under 150 on the Crohn's Disease Activity Index. [β] Reduction of ≥ 70 points on the Crohn's Disease Activity Index in 4 weeks with no changes in concomitant medication.

The adverse effect rates were similar in both groups

Conclusions

1. Rapid response to cA2.
2. Anti-TNF-α therapy with cA2 could be a new treatment option in moderate to severe Crohn's disease.
3. A single infusion of cA2 was an effective short-term treatment for patients with moderate to severe treatment-resistant Crohn's disease.
4. The long-term efficacy and safety must be determined.