

Randomized double-blind, placebo-controlled trial.

Patients with moderate-severe active Crohn's disease were randomly assigned to one of four treatments: (all infusions given 4weeks apart)

- Two infusions of placebo
  - One infusion of 3mg/kg of natalizumab followed by placebo
  - Two infusions of 3mg/kg of natalizumab (NAT3x2)
  - Two infusions of 6mg/kg natalizumab (NAT6x2)
- 5ASA, steroids, thiopurines permitted

**Primary endpoint:** Clinical remission (CDAI $\leq$ 150) at week 6

**Results:** N=248

- Clinical remission at week 6: 29% NAT3mg vs 44% NAT3x2 vs 31% (NAT6x2) and 27% placebo, p=0.757, p=0.030 and p=0.533 respectively of each one vs placebo.
- Clinical response at week 6 (decrease of more than 70 points CDAI): 59% NAT3mg vs 71% NAT3x2 vs 57% (NAT6x2) and 38% placebo, p=0.022, p<0.001 and p=0.039 respectively of each one vs placebo.
- There was a significant decrease of CRP of both double doses of NAT (3mgx2 and 6mgx2) at week 6 compared to placebo.

**Conclusion:**

Treatment with natalizumab increased the rates of clinical remission and response, improved CRP levels and quality of life in patients with active Crohn's disease.

## Natalizumab in active Crohn's Disease

**Table 2. Rates of Remission and Clinical Response.\***

Week	Placebo (N=63)	1 Infusion of 3 mg of Natalizumab/kg (N=68)	2 Infusions of 3 mg of Natalizumab/kg (N=66)	2 Infusions of 6 mg of Natalizumab/kg (N=51)	<i>no. of patients (%)</i>			
<b>Remission</b>								
Week 2	6 (10)	10 (15)	13 (20)	6 (12)				
P value		0.328	0.127	0.745				
Week 4	9 (14)	21 (31)	19 (29)	15 (29)				
P value		0.02	0.027	0.028				
Week 6 (primary end point)	17 (27)	20 (29)	29 (44)	16 (31)				
P value		0.757	0.030	0.533				
Week 8	10 (16)	19 (28)	27 (41)	22 (43)				
P value		0.107	<0.001	<0.001				
Week 12	17 (27)	19 (28)	28 (42)	20 (39)				
P value		0.992	0.042	0.122				
<b>Response</b>								
Week 2	19 (30)	31 (46)	36 (55)	22 (43)				
P value		0.081	0.004	0.136				
Week 4	18 (29)	32 (47)	41 (62)	27 (53)				
P value		0.029	<0.001	0.006				
Week 6	24 (38)	40 (59)	47 (71)	29 (57)				
P value		0.022	<0.001	0.039				
Week 8	22 (35)	38 (56)	44 (67)	28 (55)				
P value		0.018	<0.001	0.028				
Week 12	27 (43)	34 (50)	40 (61)	33 (65)				
P value		0.503	0.033	0.018				

\* Remission was defined by a score of less than 150 on the Crohn's Disease Activity Index. A response was defined by a decrease in the score of at least 70 points from base line. P values are for the comparison with the placebo group.

