2007.
Natalizumab+IFX

RCT/Natalizumab+IFX /CD/Induction

Safety and Tolerability of Concurrent Natalizumab Treatment for Patients with Crohn's Disease Not in Remission While Receiving Infliximab

Multicenter, randomized, double-blind, placebo-controlled trial. Patients with active CD (CDAI ≥ 150) were randomized to 3 IV doses of natalizumab or placebo every 4 weeks. Patients were receiving IFX every 8weeks for at least 10w prior randomization and throughout the study

Primary endpoint: Short-term safety and tolerability of natalizumab+IFX

Results: N=79
- Incidence of adverse events was similar between groups
- Mean CDAI score decreased with natalizumab + IFX but was inchanged with IFX alove (-37.7 vs +3.5, p=0.084)
- No drug interactions were noted.

Conclusion:
The combination of natalizumab plus infliximab was well tolerated. Several positive trends suggested that treating patients not in remission with infliximab plus natalizumab had greater efficacy than treatment with infliximab alone.

TABLE II. Incidence of Adverse Events Occurring in More Than 5% of Patients in Natalizumab + Infliximab Group

Adverse event	Placebo + infliximab (N = 27), n (%)	Natalizumab + infliximab (N = 52), n (%)
Headache	6 (22)	12 (23)
Fatigue	2 (7)	7 (13)
Exacerbation of Crohn's disease	4 (15)	5 (10)
Dizziness	1 (4)	5 (10)
Nasopharyngitis	3 (11)	5 (10)
Nausea	3 (11)	5 (10)
DNA antibody positive	3 (11)	4 (8)
Dyspepsia	1 (4)	4 (8)
Abdominal pain	0	3 (6)
Antinuclear antibody positive	1 (4)	3 (6)
Arthralgia	2 (7)	3 (6)
Back pain	2 (7)	3 (6)
Insomnia	1 (4)	3 (6)
Pyrexia	0	3 (6)
Upper respiratory tract infection	1 (4)	3 (6)

Note: A patient was counted only once for each type of adverse event.

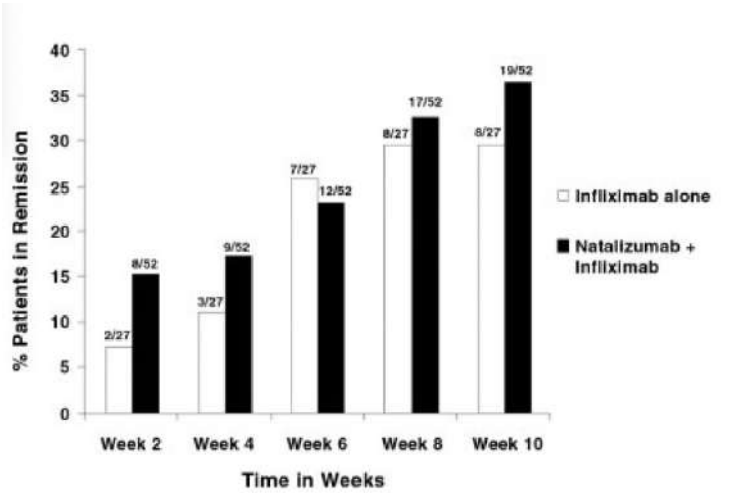

FIGURE 4. Percentage of patients in clinical remission (CDAI < 150) over time.

Sands BE et al. *(Inflamm Bowel Dis 2007;13:2–11*