Multicenter, randomized, double-blind, placebo-controlled trial. Patients with active CD were randomized to adalimumab 160/80mg, 80/40mg or placebo at weeks 0 and 2. At week 4 those who had a decrease in CDAI ≥ 70 entered maintenance and were randomized to adalimumab 40 mg eow or placebo up to 52 w.

Primary endpoint: Induction: CDAI<150 at week 4

Maintenance: CDAI <150 at week 52.

Results: N=90

- Clinical remission at w4: 33.3%, 17.6% and 13% in ADA 160/80, 80/40 and placebo respectively.
- Clinical remission at w52: 38.1% ADA vs 9.1% placebo

Conclusion:

Adalimumab is effective and well-tolerated for inducing and maintaining clinical remission in Japanese patients with moderate to severe Crohn's disease.





