# 2006. CLASSIC I

RCT/ ADA/ CD/ Induction

**Human anti-TNF monoclonal antibody (adalimumab) in Crohn's disease: The CLASSIC-I trial**

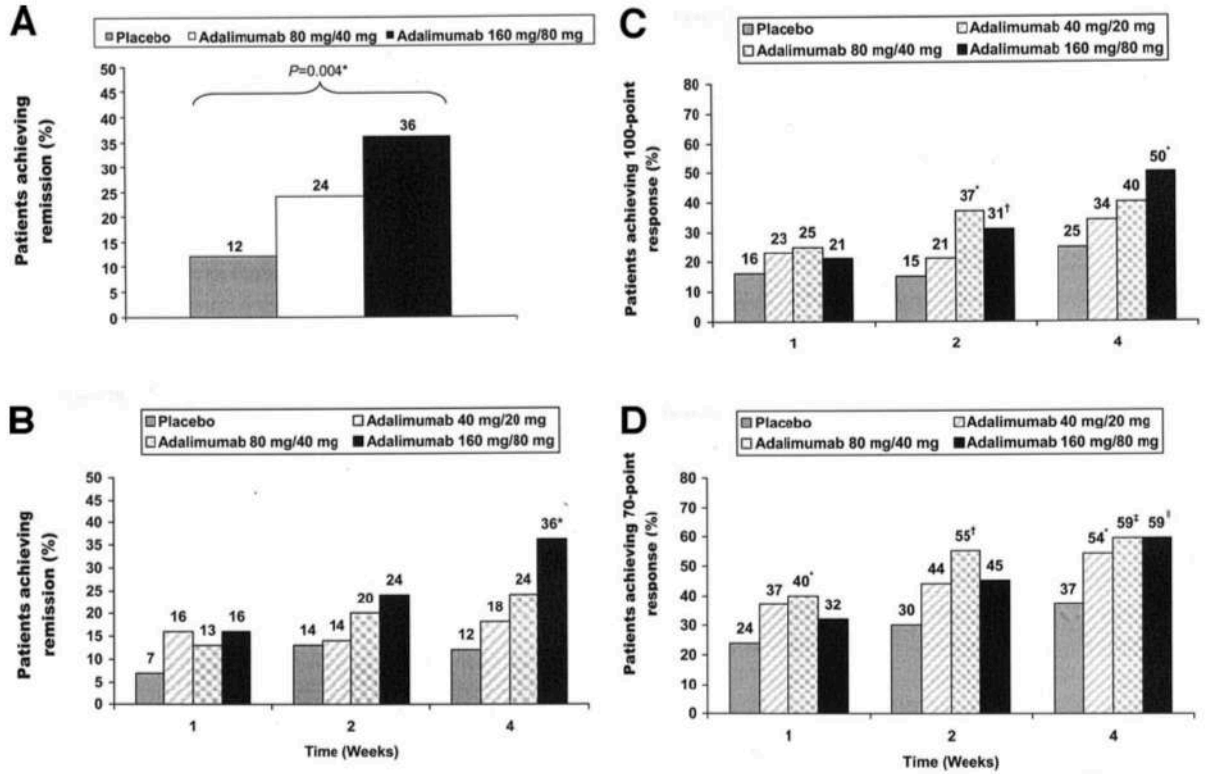
Randomized, double-blind, placebo controlled, dose-ranging trial.
Patients naïve to antiTNF
3 induction regimens: placebo at weeks 0 and 2; adalimumab 40 mg at week 0 and 20 mg at week 2; adalimumab 80 mg at week 0 and 40 mg at week 2; or adalimumab 160 mg at week 0 and 80 mg at week 2.
Aim: to evaluate the efficacy of ADA induction therapy in patients with moderate-severe CD with different doses.

- Primary outcome: Remission at week 4.

Results:

- Remission w4 in the Adalimumab groups were: 40mg/20mg (18%, p=ns); 80mg/40 mg (24%, p=ns); 160mg/80mg (36%, p=0.001) vs 12% placebo.
- Adverse events occurred at similar frequencies in all 4 treatment groups, except injection site reactions, more frequent in ADA groups.

Conclusions:
Adalimumab better than placebo in achieving remission at week 4.




Hanauer SB et al. Gastroenterology. 2006; 130: 323-333