

Randomized placebo-controlled trial. Moderate-severe CD. Open label induction Adalimumab 80 mg week 0 followed by ADA 40 mg week 2. Then at week 4 according to response patients were randomized for maintenance to: placebo vs ADA eow or ADA ew

- Co-primary end points: Clinical response (decrease in CDAI scores > 70) and clinical remission w26 & w56.
- Secondary end points: changes in IBDQ score; steroid free clinical remission w26 & w56

Results:

- W26 response: 40% ADA eow vs 47% ADA ew vs 17% pbo; $p=0.001$
- W56 response: 35% ADA eow vs 41% ADA ew vs 12% pbo; $p<0.001$
- No differences between ADA eow and ADA ew
- Difference in remission rates between ADA and placebo from w6 and maintained through w56

Conclusions:

Adalimumab eow or ew more effective than placebo maintaining remission in moderate-severe CD patients who respond to induction.

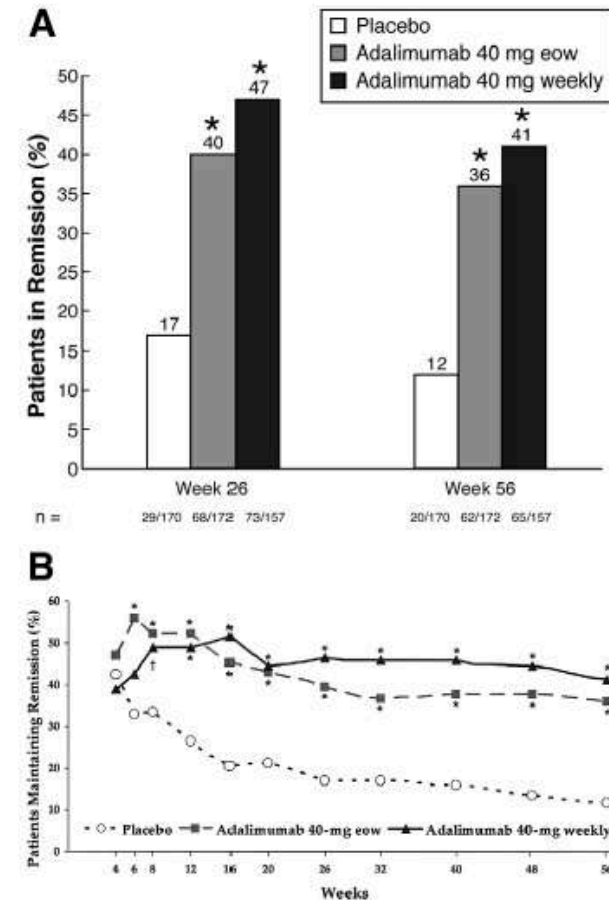


Figure 2. (A) Clinical remission at weeks 26 and 56 in randomized responder population (week-4 responders). Remission defined as a decrease in CDAI score to <150. * $P < .001$ for pairwise comparison between each adalimumab treatment group and placebo. eow, every other week. (B) Clinical remission over time in randomized responder population (week-4 responders). $P < .001$ for adalimumab vs placebo

