

Randomized, double-blind, placebo controlled trial.
Efficacy certolizumab pegol 400 mg subcut vs placebo week 0, 2, and 4 and then every 4 weeks in moderate to severe CD patients.

Randomization according CRP levels $>/<10\text{mg/L}$, steroid use and immunosuppressant.

Primary outcome:

A decrease of at least 100 points in the CDAI score at w6 and at both w6 and 26 in patients with a baseline serum CRP $>10\text{ mg/L}$.

Results:

- Response rates at w6: 35% in the certolizumab vs 27% placebo ($P = 0.02$);
- w6 and w26, the response rates were 23% and 16%, respectively ($P = 0.02$).
- At w6 and w26, the rates of remission in the two groups did not differ ($p = 0.17$).

Conclusion: In patients with moderate-to-severe Crohn's disease, induction and maintenance therapy with certolizumab pegol was associated with a modest improvement in response rates, as compared with placebo, but with no significant improvement in remission rates.

