2000. IL10 Phase 3

RCT/IL-10/ CD / efficacy & safety

Safety and Efficacy of Recombinant Human Interleukin 10 in Chronic Active Crohn's Disease

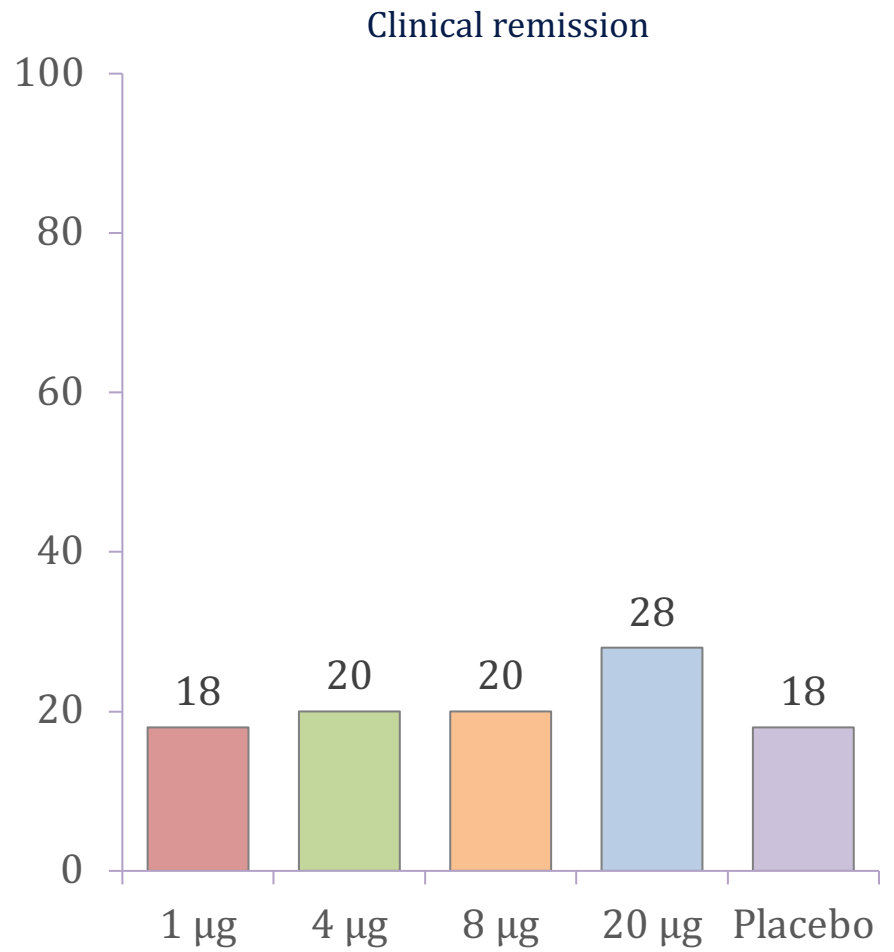
Phase 3, multicentre, randomized double-blind, placebo-controlled and sequential-escalating-doce study.
Patients with active mild-moderate CD were randomized to SC rhuIL-10 (1, 4, 8 or 20 μg /kg) or placebo once daily for 28 consecutive days.

Primary endpoint: CDAI remission (<150 points with at least a decrease of 100 points) after induction.

Results: N=329

- Clinical remission was: 1 μg, 18%; 4 μg, 20%; 8 μg, 20%; 20 μg, 28% and placebo 18%, with no statistical differences.
- Responders to rhuIL-10 showed inhibition of NF-kB p65 activation in contrast to non-responders.

Conclusion:
No differences against placebo. A tendency toward clinical improvement but not remission was observed in the 8mg/kg dose group. Up to 8 μg /kg of rhuIL-10 was well tolerated.



Schreiber S et al. Gastroenterology. 2000; 119:1461-1472