

Randomised double-blind. Moderate to severe CD patients randomised to: 130mg UST or 6mg/kg approx vs placebo.

Primary outcome for induction: clinical response w6.

Secondary outcomes: remission w8, decrease in CDAI >70 points at w3 and w6; clinical response w3, clinical remission w3&w6; change in CRP and CDAI.

Primary endpoint for maintenance: clinical remission w44.

Secondary endpoint: clinical response w44, maintenance of remission, steroid free remission.

Results:

UNITI I:

- Clinical response w6: 34.4% UST 130 vs 33.7% UST6 vs 21.5% pbo; $p < 0.003$ for both comparisons with placebo

UNITI II

- Clinical response w6: 51.7% UST130 vs 55.5% UST6 vs 28.7% pbo; $p < 0.001$ for both comparisons
- Remission w44: 52.1% USTq8 vs 48.8% USTq12 vs 35.9% pbo; $p = 0.005$, $p = 0.04$

Conclusion:

Ustekinumab superior to placebo for induction and maintenance in moderate-severe CD.

Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease

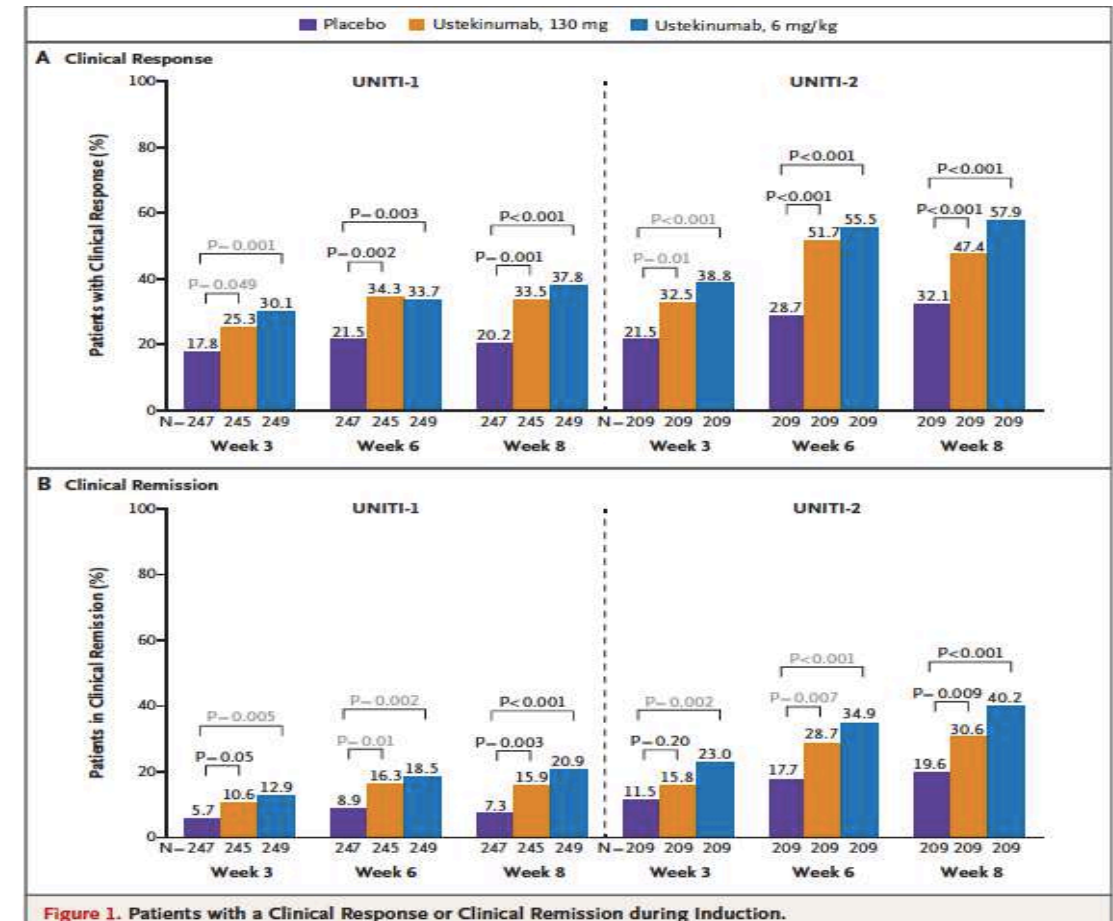


Figure 1. Patients with a Clinical Response or Clinical Remission during Induction.

