

Ustekinumab therapy for moderately to severely active pediatric Crohn's disease: UNITI Jr study safety and efficacy results in patients weighing at least 40 kg

Phase 3 randomized-controlled trial.
Pediatric patients with CD received a single IV weight-tiered induction dose of ustekinumab. After 8 weeks, patients were randomized to q8w or q12w maintenance SC.

Primary endpoints: Clinical remission at week 8.

Results: N=48

- At week 8 clinical remission was achieved in 52.1%.
- Clinical remission at week 52 was 60% q12w vs 43.5% q8w.

Conclusion:

Ustekinumab induction and maintenance therapy was effective and safe through 52 weeks in pediatric patients weighing at least 40 kg with moderately to severely active CD.

Clinical remission at week 8