Ustekinumab Intravenous Reinduction after Secondary Loss of Response in Patients with Crohn's Disease

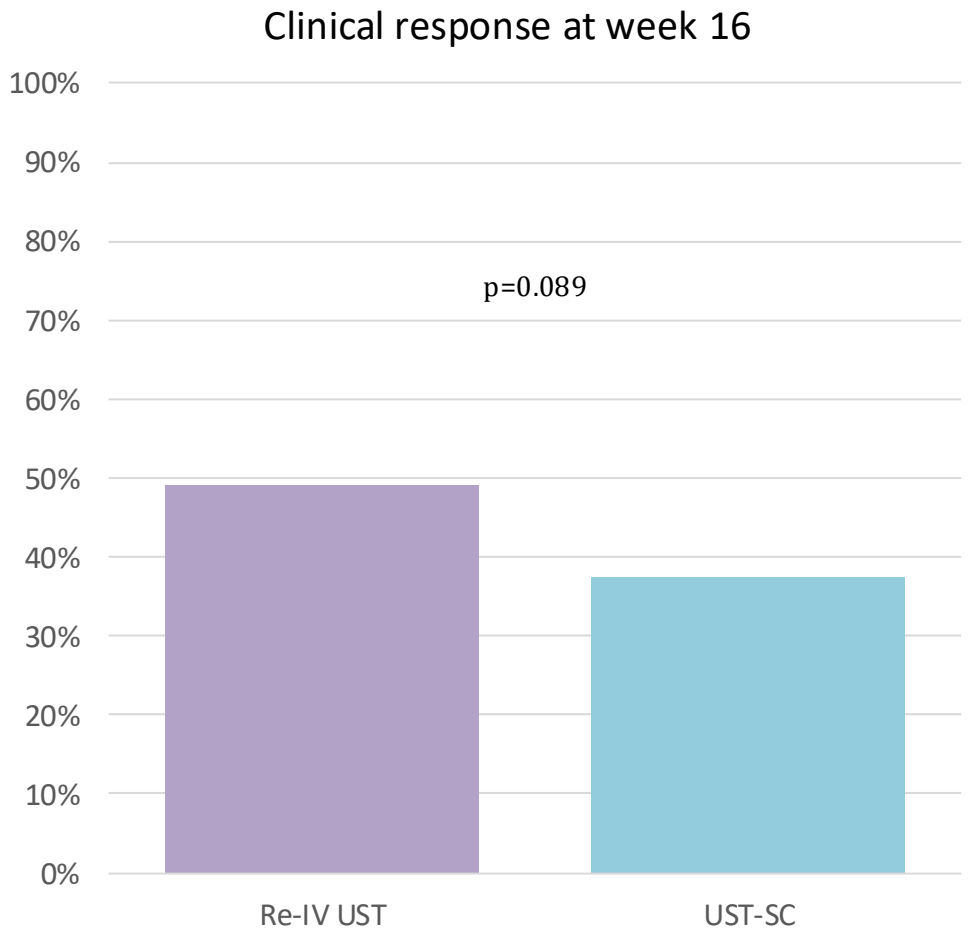
Multicenter double-blind, randomised placebo-controlled phase 3b trial .
Patients with mod-severe CD who had secondary los of response to ustekinumab every 8 weeks (q8w) were randomized to ustekinumab IV reinducction or placebo and the same maintenance.

Primary endpoint: Clinical response (CDAI decrease of >=100 or CDAI<150) at week 16.

Results: N=215

- At week 16 clinical response was 49.1% reinduction vs 37.4% placebo, p=0.089
- At week 16 and 24 clinical remission was not significantly different between groups.
- At week 16 normalization of CRP and/or FC was 33.3% reinduction vs 14.9% control, p=0.004
- Endoscopic remission at week 16 was 16.6.% reinduction vs 5.2% control.

Conclusion: Primary endpoint of clinical response was not met at Week 16, ustekinumab IV reinduction showed numerical improvements in inflammatory biomarkers and endoscopic outcomes. Safety and immunogenicity results were consistent with the established profile of ustekinumab.



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