

The effect of dose-intensification after secondary loss of response to ustekinumab in Crohn's disease: Results of the REScUE study

Multicenter investigator-initiated, randomized, placebo-controlled trial in Belgium.

Adult patients with CD treated with ustekinumab on maintenance 90mg q8w who experienced secondary loss of response were given a single IV re-induction with 6mg/kg and were randomized to continue on subcutaneous 90mg q4w or q8w until week 48.

Primary endpoint: Steroid-free clinical remission at week 48 and fecal calprotectin <250 and no steroids in the 90 days prior.

Results: N=108

- At week 48, steroid free clinical remission was achieved in 15% q4w vs 19% q8w, p=0.5

Conclusion:

In patients with CD and secondary loss of response to ustekinumab, dose-intensification with a single IV administration and followed by 4 weekly subcutaneous dosing of ustekinumab was not more effective than one IV administration followed by 8 weekly SC dosing of ustekinumab

Steroid-free clinical remission week 48