

Randomized, placebo controlled, double-blind, phase 3 trial. Efficacy and safety of Etrolizumab. Patients naïve to antiTNF with moderate-to-severe UC.

Etrolizumab sc 105mg e4w. Those responding at w10 induction, entered the double blind vs pbo until w62.

Primary endpoint: remission w62 in modified ITT analysis.

Secondary endpoints: steroid free remission w6, endoscopic improvement, sustained remission, endoscopic remission, histologic remission.

Results:

- Primary outcome: w62 remission: 29.6% ETR vs 20.6% pbo, $p=0.19$
- Secondary outcomes: ETR superior than pbo in endoscopic improvement, histologic remission and endoscopic remission.
- Serious adverse events in pbo than ETR, 8% vs 9%, no differences.

Conclusions:

No differences between ETR and placebo in the primary endpoint.

