Tofacitinib versus oral prednisolone for induction of remission in moderately active ulcerative colitis (ORCHID): A prospective, open-label, randomized, pilot study

Single-cennter, open-laberl, randomized, active-controlled pilot study.

Adult patients with moderately active UC were randomised to prednisolone 40mg daily(tapered by 5 mg/week) or tofacitinib (10mg twice daily) for 8 weeks.

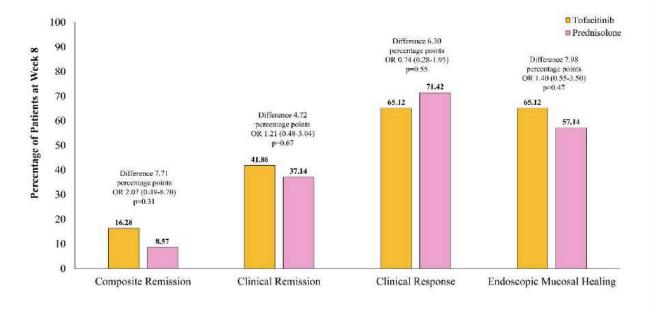
<u>Primary endpoint:</u> Composit remission (defined as total Mayo clinic score ≤ 2 , with endoscopic subscore of 0 and calprotectin < 100 mcg/g) at 8 weeks.

Results: N=78

- At week 8, composite endpoint was met in 16.28% TOFA vs 8.57% PREDNI groups, OR 2.07, 95%CI 0.49-8.70; p=0.31
- Clinical remission at week 8: 41.86% TOFA vs 37.14% PREDNI (p=0.67)
- Time to symptomatic remission, biomarker remission, endoscopic remission and composite of symptomatic+ biomarker did not differ statistically among groups

Conclusion:

In patients with moderately active ulcerative colitis, there was no difference in the efficacy and safety of tofacitinib and oral prednisolone for induction of remission at 8 weeks



Primary End Point

Major Secondary End Points