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Summary

TREATMENT WITH NORUCHOLIC ACID DELAYS THE TIME TO ULCERATIVE COLITIS FLARES IN PATIENTS WITH PRIMARY SCLEROSING CHOLANGITIS WITH INFLAMMATORY BOWEL DISEASE: SUBGROUP ANALYSES FROM THE PHASE 3 RANDOMIZED CONTROLLED TRIAL NUC-5/PSC

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Norucholic acid delayed time to first colitis flare in PSC patients with IBD (hazard ratio 0.35, p=0.004) while maintaining efficacy on the combined liver endpoint regardless of IBD status.

KEY POINTS

- 13.9% of norucholic acid patients versus 30.0% of placebo patients with ulcerative colitis experienced at least one colitis-related event by week 96.
- Time to first colitis event was significantly longer with norucholic acid than placebo (hazard ratio 0.35, p=0.004).
- Among patients with IBD at baseline, 13.9% receiving norucholic acid versus 7.1% receiving placebo achieved the combined primary endpoint of no worsening in Ludwig histologic stage with reduction in alkaline phosphatase to less than 1.5 times upper limit of normal at week 96.
- No worsening in Ludwig histologic stage was observed in 54.0% of norucholic acid patients versus 37.5% of placebo patients with IBD (p=0.021).
- Fewer than 5% of patients in either arm received biologics for IBD during the trial, and rates of IBD progression and treatment escalation were low in both arms.
- Patients enrolled had mild IBD (mean baseline CAI scores 1.5 for norucholic acid, 1.2 for placebo), and IBD medications other than 5-aminosalicylates or probiotics were prohibited during the trial.

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