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Summary

STUDY OF TOFACITINIB FOR THE TREATMENT OF CHRONIC POUCHITIS (STOPIT): AN OPEN LABEL INDUCTION WITH RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED MAINTENANCE VS WITHDRAWAL

Jakob Begun

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In this randomized controlled trial, tofacitinib 10mg twice daily achieved a 74% clinical response rate in chronic pouchitis induction, and tofacitinib 5mg twice daily was superior to placebo in maintaining response (50% vs 10%, p=0.01).

KEY POINTS

- Clinical response was 59% at week 8 with tofacitinib 10mg twice daily, and 74% overall after extended induction to week 16 in 53 patients with chronic antibiotic-dependent or refractory pouchitis
- In the maintenance phase, clinical response at week 24 was 50% with tofacitinib 5mg twice daily versus 10% with placebo (delta 40%, p=0.01)
- Endoscopic response at week 8 was 42% and mPDAI remission was 27%
- Endoscopic friability, nocturnal symptoms, and lower baseline serum IL-18 predicted response to tofacitinib at end of induction
- No new safety findings emerged during follow-up of up to 175 days, and adverse events were consistent with previous ulcerative colitis trials
- This is the first randomized placebo-controlled trial of tofacitinib in chronic pouchitis and demonstrated effectiveness in patients previously treated with vedolizumab

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