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Summary

PROSPECTIVE VALIDATION OF AN ALGORITHMIC TOOL TO SAFELY CEASE ANTI-TUMOR NECROSIS FACTOR THERAPY IN CROHN'S DISEASE: A STEPPED WEDGE CLUSTER RANDOMIZED TRIAL

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In Crohn's disease patients with a low predicted relapse risk (≤33.3% per the CEASE tool), stopping anti-TNF therapy was not non-inferior to continuing treatment, with a 1-year relapse rate of 36% versus 2% respectively.

KEY POINTS

- This stepped-wedge cluster randomised trial included 228 patients on infliximab or adalimumab in steroid-free remission for at least 6 months at 19 Dutch hospitals.
- At one year, protocol-defined relapse occurred in 2.07% (95% CI 0-4.74%) of patients continuing anti-TNF versus 36.02% (95% CI 24.66-45.67%) of those who stopped, exceeding the pre-specified 30% non-inferiority margin.
- When including all suspected relapses prompting treatment restart, the 1-year relapse rate was 44.48% in the cessation group versus 2.07% in the continuation group.
- Among patients who relapsed after stopping anti-TNF, 91.8% achieved clinical remission within 6 months of retreatment, mostly with anti-TNF agents.
- The CEASE prediction tool, which incorporates clinical and biochemical features, did not adequately identify patients who could safely discontinue anti-TNF therapy.

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