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Summary

HIGH EFFICACY OF SUBCUTANEOUS INFLIXIMAB INDUCTION WITH AND WITHOUT CONCOMITANT IMMUNOMODULATORS FOR ACTIVE CROHN'S DISEASE: TOPLINE RESULTS OF THE DIRECT-CD STUDY

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UEG Week Barcelona 2026 | Presentation

IBD

October 19, 2026

DIRECT-CD trial shows subcutaneous infliximab monotherapy achieved comparable efficacy to combination therapy for induction and maintenance in moderate-to-severe Crohn's disease, though formal non-inferiority could not be demonstrated due to early termination.

KEY POINTS

- The primary composite endpoint of corticosteroid-free clinical remission and endoscopic response at week 26 was achieved in 62.1% of monotherapy patients versus 54.8% of combination therapy patients (risk difference +7.2%, 95% CI −13.3% to +26.8%), but formal non-inferiority could not be demonstrated as the confidence interval crossed the −10% margin.
- Infliximab serum concentrations were comparable between monotherapy and combination therapy at all timepoints, including week 26 (17.5 mg/L versus 20.7 mg/L, p=0.267).
- Endoscopic remission, endoscopic response, and corticosteroid-free clinical remission rates were similar between groups, with corticosteroid-free clinical remission achieved in 72.4% of monotherapy versus 67.7% of combination therapy patients.
- Anti-drug antibody development was not significantly different at week 26 (56.0% monotherapy versus 50.0% combination therapy), though a numerical trend toward higher early antibody formation was observed in the monotherapy group.
- Three serious adverse events occurred (two in combination therapy group: Crohn's disease flare and severe nausea; one in monotherapy group: ciprofloxacin-induced tendinitis), with all patients recovering and no opportunistic infections, malignancies, or deaths.

– The study was prematurely terminated due to slow recruitment after enrolling 60 of a planned 158 patients; a Bayesian analysis suggested a 91.4% posterior probability of non-inferiority had the full cohort been enrolled.

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