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Summary

CLINICAL EFFICACY, THERAPEUTIC DRUG MONITORING AND NOCEBO EFFECT FOLLOWING NON-MEDICAL BIOSIMILAR SWITCH IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE: A PROSPECTIVE OBSERVATIONAL STUDY

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IBD

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A prospective 24-week study of 210 IBD patients undergoing non-medical biosimilar switch found no significant changes in clinical remission rates, biomarkers, therapeutic drug levels, or anti-drug antibodies despite nocebo effects in 13.3% of patients.

KEY POINTS

- Clinical remission rates remained stable across all time points (89.0% pre-switch to 90.8% at week 24, p=0.129), with sustained remission in 79.4% at week 12 and 69.6% at week 24.
- Biomarker remission showed no significant differences before or after switch: CRP remission ranged 73.0-81.3% (p=0.343) and fecal calprotectin remission 71.7-78.3% (p=0.829).
- Therapeutic drug levels remained stable (83.0-85.3%, p=0.597) and anti-drug antibody prevalence was unchanged, with adalimumab antibodies at 0-4.1% and infliximab antibodies at 0-3.0%.
- Nocebo effects were observed in 13.3% of patients and 4.3% discontinued biosimilar therapy, but these did not translate into significant clinical, biomarker, or drug monitoring changes.
- This study is relevant for gastroenterologists managing IBD patients undergoing biosimilar switches and supports the safety and efficacy profile of biosimilars in clinical practice.

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