

AN INTERNATIONAL CONSENSUS ON APPROPRIATE MANAGEMENT OF CORTICOSTEROIDS IN CLINICAL TRIALS IN INFLAMMATORY BOWEL DISEASE

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Poster

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An international Delphi consensus of 45 IBD RCT experts developed standardised recommendations for corticosteroid management across screening, induction, and maintenance phases of clinical trials in moderately-to-severely active inflammatory bowel disease.

KEY POINTS

- Key recommendations include a 2-week stable corticosteroid dosing period before screening, maximum baseline dosages of 20 mg/day prednisone equivalents (or 9 mg/day budesonide), and exclusion of patients who received intravenous corticosteroids during screening.
- During induction, corticosteroid dosages should be fixed for at least 2 weeks after randomisation, with tapering beginning at ≤ 2 weeks of induction and mandated by trial protocol rather than investigator discretion.
- The consensus recommends a unified tapering protocol of 5 mg prednisone equivalents per week, while enteric- and colonic-release budesonide should be discontinued without tapering.
- Patients who deviate from the tapering schedule by receiving dosage escalation during maintenance should be regarded as having failed treatment, and only patients using corticosteroids at maintenance start should form the denominator for corticosteroid-free remission rates.
- These recommendations aim to minimise inappropriate prolonged corticosteroid exposure, standardise practices across trials, improve comparability between studies, and reduce steroid-related harm to participants.

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