AN INTERNATIONAL CONSENSUS ON THE DESIGN OF CLINICAL TRIALS FOR ADVANCED COMBINATION TREATMENT (ACT) IN INFLAMMATORY BOWEL DISEASE

Claire Parker

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An international expert panel using Modified RAND/UCLA methodology developed consensus recommendations for standardising clinical trial design of advanced combination therapies in inflammatory bowel disease.

KEY POINTS

- Advanced combination treatment should pair drugs with distinct mechanisms of action, avoiding two agents targeting the same biological pathway such as two anti-TNF therapies, while combinations like sphingosine-1-phosphate receptor modulators with α4β7 inhibitors were deemed appropriate.
- Trials should include patients who have failed conventional therapy or are at high risk for disease complications, with efficacy and safety compared against each monotherapy component using co-primary endpoints of clinical remission and endoscopic response for Crohn's disease and composite clinical and endoscopic remission for ulcerative colitis.
- Primary outcome timepoints were recommended at Week 8 to 14 for induction and Week 48 or 52 for maintenance, with safety outcomes including adverse events, infections, and hospitalisations.
- Precision medicine approaches are considered essential, requiring serial collection of blood, serum, plasma, stool, and mucosal biopsies for immune cell, transcriptomic, metabolomic, pharmacokinetic, and microbiome analyses throughout the trial.
- The 17-member expert panel evaluated 287 statements across six domains to address the current lack of standardised guidance for designing advanced combination therapy trials in IBD.

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