gastrointestinal tumours, colorectal

THE IDEA (INTERNATIONAL DURATION EVALUATION OF ADJUVANT CHEMOTHERAPY) COLLABORATION: A PROSPECTIVE POOLED NON-INFERIORITY ANALYSIS OF > 11,500 PATIENTS FROM 6 PHASE III TRIALS OF ADJUVANT THERAPY DURATION WITH FOLFOX (FOLFOX4 OR MFOLFOX6) OR XELOX (3 VS. 6 MONTHS) FOR STAGE III COLON CANCER


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Background: The IDEA collaboration was established to prospectively pool and analyze data from 6 randomized trials to answer whether 3-months of oxaliplatin-based adjuvant therapy (FOLFOX4/modified FOLFOX6 or XELOX) is non-inferior to the current standard 6-month treatment in pts with stage III colon cancer, with a primary endpoint of 3 years disease-free survival. A 3 month duration of oxaliplatin-based adjuvant therapy would provide substantial advantages in toxicity, cost, and patient convenience.

Design: Members of the IDEA have agreed to pool data from their individual trials (SCOT-UK led with accrual from Australia, Denmark, Spain, Sweden & New Zealand, final accrual 4027 pts; TOSCA-Italy, final 2436 pts; GERCOR/PRODIGE-France, final 2000 pts; CALGB/SWOG-US/Canada, current accrual 1600 pts; ACHIEVE-Japan, final 1200 pts; HORG-Greece, current 600 pts) to allow a definitive analysis. IDEA members prospectively agreed on eligibility criteria, treatment administration, primary endpoints, and statistical analysis plan. May 1, 2014 total IDEA accrual exceeds 11,500 pts. This sample size will provide 3390 DFS events to provide 90% power to declare non-inferiority, based on an expected 3 year DFS rate in the control group of 72%, with a one-sided alpha of 0.025 if the true DFS HR is 1.12. A single pooled interim analysis, conducted by an external Data Monitoring Board (DMB), is prospectively specified when 50% of planned DFS events have been observed; this analysis occurred in May 2014 and the DMB recommended the trial continue per protocol with no modifications.

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