TPS3645 Poster Session

Platform study of circulating tumor DNA–directed adjuvant chemotherapy in colon cancer (CLAUDIA Colon Cancer, KCSG CO22-12).

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Background: Tumor-informed circulating tumor DNA (ctDNA) analysis allows for the sensitive detection of minimal residual disease (MRD) and has the potential to enhance patient stratification for adjuvant chemotherapy (AC). In patients with stage II-III colon cancer, we demonstrated that postoperative MRD is associated with poor disease-free survival (DFS) despite oxaliplatin-based AC. We hypothesize that intensifying AC in colon cancer patients with postoperative MRD may improve survival outcomes. **Methods:** This multi-center platform trial (NCT05534087) consists of a prospective observational study (Part 1) and an interventional randomized trial (Part 2). In Part 1, approximately 1,200 patients with colon cancer will be screened for MRD at 3–6 weeks postoperatively using atumor-informed hybrid-capture-based ctDNA MRD assay (CancerDETECT) which tracks ~100 patient-specific somatic variants identified through tumor whole-exome sequencing. Key eligibility criteria include: age ≥19 years, ≤6 weeks post-curative resection, pathological diagnosis of colon cancer, stage III or stage II with high-risk features requiring AC with FOLFOX/CAPOX, and no macroscopic residual disease. All patients in Part 1 will complete 3 months of standard adjuvant FOLFOX/CAPOX while awaiting MRD results. After 3 months of AC, MRD-negative patients are managed at the investigator's discretion. Patients with MRD positivity will be screened for Part 2 clinical trial following the completion of initial 3 months of standard AC titled "*Randomized Controlled Phase III Trial of Treatment Intensification in Stage II–III Colon Cancer Patients with Positive MRD after Curative Resection*." Part 2 investigates the superiority of an experimental arm (modified FOLFIRINOX for 3 months) compared to a control arm (FOLFOX/CAPOX for 3 months). The primary endpoint is the 3-year DFS rate, while secondary endpoints include the 5-year overall survival rate, treatment-related adverse events, treatment adherence, and patient-reported outcomes. A total of 236 patients will be enrolled, assuming a hazard ratio of 0.64, 80% power, a two-sided alpha of 0.05, and a 10% dropout rate. As of November 2024, 630 patients have been screened in Part 1, and 99 patients have been enrolled in Part 2. Both studies are ongoing, and an interim analysis is planned after ≥ 48 events. Clinical trial information: NCT05534087. Research Sponsor: National R&D Program for Cancer Control through the National Cancer Center (NCC) funded by the Ministry of Health & Welfare, Republic of Korea (HA22C0062).