Multi-center phase III trial of Adjuvant Chemoradiotherapy in Stomach Tumors 2 (ARTIST 2)


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Introduction: Treatment of gastric cancer (GC) has some notable differences between Asia and Western countries including the extent of surgery and the type of adjuvant therapy. In ARTIST trial comparing adjuvant chemotherapy involving capecitabine plus cisplatin with chemoradiotherapy, we reported comparable disease-free survival (DFS) in Korean patients with D2-resected GC. In subset analyses, patients with node-positive disease and intestinal type GC may have benefit with the addition of radiotherapy to adjuvant chemotherapy.

Methods: ARTIST 2 (ClinicalTrials.gov, NCT0176146) is a 3-arm, multi-center, open-label phase III trial comparing adjuvant chemotherapy involving S-1 (40 mg/m2 bid 4-weeks-on/2-weeks-off) for one year (arm A) with S-1 plus oxaliplatin (SOX, S-1 40 mg/m2 bid 2-weeks-on/1-week-off plus oxaliplatin 130 mg/m2 iv on day 1) for 8 cycles (arm B) and chemoradiotherapy (arm C). Arm C patients receive SOX for 2 cycles, then concurrent chemoradiotherapy 45 Gy with S-1 40 mg bid daily, followed by additional SOX for 4 more cycles. Patients are randomized 1:1:1 with 3 strata: stage (II or III), type of surgery (subtotal or total gastrectomy) and Lauren classification (diffuse or intestinal type). Eligibility criteria include gastric or gastro-esophageal junction adenocarcinoma, D2 or higher surgery with no residual disease, pathologic stages 2 or 3, lymph node positive disease. Primary endpoint is DFS, and secondary endpoints include overall survival, safety, QOL and molecular biomarkers. To test if experimental arms (arm B or C) lower the hazard of recurrence by 50% (i.e., HR 1.5) compared to arm A, we need 900 patients (300 per arm) with 90% of overall statistical power. First patient entered onto the study in Feb 2013. As of Feb 2015, a total of 195 (22% of target) patients were recruited by 9 Korean tertiary centers.