**PHASE III STUDY OF APATINIB IN ADVANCED GASTRIC CANCER: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL**


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**Introduction:** Molecular targeted therapy has made great progress in the treatment of gastric cancer. This paper reports the outcome of a phase III clinical study of apatinib, as an oral small molecular of VEGFR-2 tyrosine kinase inhibitor, in the treatment of patients with advanced gastric cancer who prior failure to second-line chemotherapy. This study may provide a new treatment options and leading a new hope for these patients.

**Methods:** This is a multicenter, randomized, double-blind, placebo-controlled phase 3 trial. Apatinib or matching placebo, 850 mg, po, qd, 28 days as one cycle. Primary outcomes were overall survival. Study randomization was centralized and stratified according to the number of metastatic sites (≤2 or >2). Planned to enroll 270 cases: 180 of apatinib and 90 of placebo. This trial was registered with ClinicalTrials.gov, number NCT01512745.

**Results:** The patient baseline characteristics were similar in two arms with respect to age, history of the disease, gender, ECOG scores, number of metastatic sites, pathological grading, clinic stage and therapy history (P > 0.05). As to efficacy, median overall survival (mOS) was significantly prolonger in the apatinib group compared with in the placebo group (195 days versus 140 days; HR= 0.71; 95% CI (0.54 – 0.94); P < 0.016). Median progression-free survival (mPFS) was also prolonged in the apatinib group compared with the placebo group (78 days versus 53 days, HR = 0.44, 95% CI (0.33 – 0.61), P < 0.0001). The objective response rates (ORR) of apatinib group and placebo group were 2.84% and 0.00% respectively. As to safety, treatment of apatinib group was generally well tolerated. Most of the adverse reactions could be managed by dose interruptions or reductions. Grade 3/4 adverse reactions that occurred in more than 2% of patients were hypertension, anorexia, elevated aminotransferase.

**Conclusion:** This study further confirmed the efficacy and safety of apatinib in patients with advanced gastric cancer. 850 mg, qd is the recommended dose for clinical use.