

## **Phase II study with oxaliplatin and S-1 for patients with metastatic colorectal cancer**

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### **Abstract**

**Background:** To evaluate the efficacy and safety of the combination of oxaliplatin and S-1 (OS) in treating metastatic colorectal cancer.

**Patients and methods:** Eligible patients were those with measurable lesions, no previous history of chemotherapy (except adjuvant chemotherapy), an age of 18 to 70 years, and an ECOG PS of 0-2. Oxaliplatin 130 mg/m<sup>2</sup> was administered intravenously on day 1, and S-1 40 mg/m<sup>2</sup> b.i.d. was administered orally on days 1-14, every 3 weeks.

**Results:** Forty-eight patients (median age, 56 years) were enrolled: 23 had colon cancer; seven, rectosigmoid colon cancer; and 18, rectal cancer. Of the 48 patients, 31 were diagnosed with metastatic cancer, and 17 had relapsed cancer after surgery, with adjuvant chemotherapy or chemoradiotherapy. In total, 413 cycles were administered (median, 6 per patient; range, 2-24). Toxicity was evaluated in 48 patient, and response, in 46. Major toxicities were grade 3/4 thrombocytopenia (13%) and neutropenia (10%). The overall response rate was 54% (95% CI, 40-68%). The median time to progression and median survival time were 8.5 (95% CI, 6.2-10.9) months and 27.2 (95% CI, 20.3-34.0) months, respectively.

**Conclusions:** These data suggest that the OS regimen is effective and well tolerated in patients with advanced colorectal cancer.