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# S-1 plus cisplatin versus S-1 alone for first-line treatment of advanced gastric cancer (SPIRITS trial): a phase III trial

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## Summary

### Background

Phase I/II clinical trials of S-1 plus cisplatin for advanced gastric cancer have yielded good responses and the treatment was well tolerated. In this S-1 Plus cisplatin versus S-1 In RCT In the Treatment for Stomach cancer (SPIRITS) trial, we aimed to verify that overall survival was better in patients with advanced gastric cancer treated with S-1 plus cisplatin than with S-1 alone.

### Methods

In this phase III trial, chemotherapy-naive patients with advanced gastric cancer were enrolled betweeen March 26, 2002, and Nov 30, 2004, at 38 centres in Japan, and

randomly assigned to S-1 plus cisplatin or S-1 alone. In patients assigned to S-1 plus cisplatin, S-1 (40â€“60 mg depending on patient's body surface area) was given orally, twice daily for 3 consecutive weeks, and 60 mg/m$^2$ cisplatin was given intravenously on day 8, followed by a 2-week rest period, within a 5-week cycle. Those assigned to S-1 alone received the same dose of S-1 twice daily for 4 consecutive weeks, followed by a 2-week rest period, within a 6-week cycle. The primary endpoint was overall survival. Secondary endpoints were progression-free survival, proportions of responders, and safety. Analysis was by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00150670.

Findings

305 patients were enrolled; seven patients were ineligible or withdrew consent, therefore, 148 patients were assigned to S-1 plus cisplatin and 150 patients were assigned to S-1 alone. Median overall survival was significantly longer in patients assigned to S-1 plus cisplatin (13Â·0 months [IQR 7Â·6â€“21Â·9]) than in those assigned to S-1 alone (11Â·0 months [5Â·6â€“19Â·8]; hazard ratio for death, 0Â·77; 95% CI 0Â·61â€“0Â·98; p=0Â·04). Progression-free survival was significantly longer in patients assigned to S-1 plus cisplatin than in those assigned to S-1 alone (median progression-free survival 6Â·0 months [3Â·3â€“12Â·9] *vs* 4Â·0 months [2Â·1â€“6Â·8]; p<0Â·0001). Additionally, of 87 patients assigned S-1 plus cisplatin who had target tumours, one patient had a complete response and 46 patients had partial responses, ie, a total of 54% (range 43â€“65). Of 106 patients assigned S-1 alone who had target tumours, one patient had a complete response and 32 had partial responses, ie, a total of 31% (23â€“41). We recorded more grade 3 or 4 adverse events including leucopenia, neutropenia, anaemia, nausea, and anorexia, in the group assigned to S-1 plus cisplatin than in the group assigned to S-1 alone. There were no treatment-related deaths in either group.

Interpretation

S-1 plus cisplatin holds promise of becoming a standard first-line treatment for patients with advanced gastric cancer.

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