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Adjuvant imatinib mesylate increases recurrence free survival (RFS) in patients with completely resected localized primary gastrointestinal stromal tumor (GIST): North American Intergroup Phase III trial ACOSOG Z9001.

Adjuvant imatinib mesylate increases recurrence free survival (RFS) in patients with completely resected localized primary gastrointestinal stromal tumor (GIST): North American Intergroup Phase III trial ACOSOG Z9001.

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This trial was supported by a grant from the National Cancer Institute: U10-CA76001

Short Title:
Adjuvant imatinib in primary GIST

Background: Imatinib benefits over 80% of patients with metastatic GIST but whether it is effective in the adjuvant setting after complete resection of primary GIST is unknown.

Methods: As of April 11, 2007, 708 patients who underwent complete gross resection of a primary GIST measuring at least 3 cm and expressing KIT had been randomized in a double-blind fashion to 1 year of imatinib 400 mg daily or placebo. Upon recurrence, treatment assignment was unblinded and patients allowed to cross over to imatinib if they had been on placebo or increase the daily dose of imatinib to 800mg for those already receiving drug. The primary endpoint of the trial was RFS.

Results: Accrual to the trial was halted based on a recommendation of the ACOSOG External Data Monitoring Committee based on the results of a planned interim analysis of 644 evaluable patients. Median follow-up time in recurrence-free patients was 1.2 years. 21% of the expected events had occurred. Patients assigned to the imatinib arm had a 1 year RFS of 97% while those assigned to the placebo arm had a 1 year RFS of 83%, with a hazard ratio of 0.325 (95% CI 0.198-0.534), and a nominal unadjusted log-rank p-value of 0.0000014. Overall survival is immature, but at this time there is no difference in overall survival between the two treatment arms. Patients will continue to be followed per protocol, for up to 10 years. Imatinib therapy was well tolerated by most patients.

Conclusions: Imatinib increases RFS when administered following the complete resection of primary GIST.

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