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Titel des Beitrags: One vs three years of adjuvant imatinib for operable gastrointestinal stromal tumor: a randomized trial.

Abstract: Adjuvant imatinib administered for 12 months after surgery has improved recurrence-free survival (RFS) of patients with operable gastrointestinal stromal tumor (GIST) compared with placebo. To investigate the role of imatinib administration duration as adjuvant treatment of patients who have a high estimated risk for GIST recurrence after surgery. Patients with KIT-positive GIST removed at surgery were entered between February 2004 and September 2008 to this randomized, open-label phase 3 study conducted in 24 hospitals in Finland, Germany, Norway, and Sweden. The risk of GIST recurrence was estimated using the modified National Institutes of Health Consensus Criteria. Imatinib, 400 mg per day, orally for either 12 months or 36 months, started within 12 weeks of surgery. The primary end point was RFS; the secondary end points included overall survival and treatment safety. Two hundred patients were allocated to each group. The median follow-up time after randomization was 54 months in December 2010. Diagnosis of GIST was confirmed in 382 of 397 patients (96%) in the intention-to-treat population at a central pathology review. KIT or PDGFRA mutation was detected in 333 of 366 tumors (91%)
available for testing. Patients assigned for 36 months of imatinib had longer RFS compared with those assigned for 12 months (hazard ratio [HR], 0.46; 95% CI, 0.32-0.65; P < .001; 5-year RFS, 65.6% vs 47.9%, respectively) and longer overall survival (HR, 0.45; 95% CI, 0.22-0.89; P = .02; 5-year survival, 92.0% vs 81.7%). Imatinib was generally well tolerated, but 12.6% and 25.8% of patients assigned to the 12- and 36-month groups, respectively, discontinued imatinib for a reason other than GIST recurrence. Compared with 12 months of adjuvant imatinib, 36 months of imatinib improved RFS and overall survival of GIST patients with a high risk of GIST recurrence. clinicaltrials.gov Identifier: NCT00116935.