

Efficacy of Sequential High-Dose Doxorubicin and Ifosfamide Compared With Standard-Dose Doxorubicin in Patients With Advanced Soft Tissue Sarcoma: An Open-Label Randomized Phase II Study of the Spanish Group for Research on Sarcomas.

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PURPOSE: To assess the progression-free survival (PFS) and antitumor response to standard-dose doxorubicin compared with sequential dose-dense doxorubicin and ifosfamide in first-line treatment of advanced soft tissue sarcoma. **PATIENTS AND METHODS:** Patients with measurable advanced soft tissue sarcoma, Eastern Cooperative Oncology Group (ECOG) performance status (PS) < 2, between the ages 18 and 65 years, and with adequate bone marrow, liver, and renal function were entered in the study. The stratifications were: ECOG PS (0 v 1), location of metastases, and potentially resectable disease. Patients were randomly assigned to either doxorubicin 75 mg/m² given as a bolus injection every 3 weeks for 6 cycles (arm A) or doxorubicin at 30 mg/m² per day for 3 consecutive days once every 2 weeks for 3 cycles followed by ifosfamide at 12.5 g/m² delivered by continuous infusion over 5 days once every 3 weeks for 3 cycles with filgastrim or pegfilgastrim support (arm B). **RESULTS:** Between December 2003 and September 2007, 132 patients were entered onto the study. Febrile neutropenia, asthenia, and mucositis were more frequent in the arm B. The interim preplanned analysis for futility allowed the premature closure. Objective responses were observed in 23.4% of assessable patients in arm A and 24.1% in arm B. PFS was 26 weeks in the arm A and 24 weeks in arm B (P = .88). Overall survival did not differ between the two therapeutic arms (P = .14). **CONCLUSION:** Single-agent doxorubicin remains the standard treatment in fit patients with advanced soft tissue sarcoma.