

Clinical Study

Phase II Trial of Doxorubicin Plus Escalated High-Dose Ifosfamide in Patients With Advanced Soft Tissue Sarcomas of the Adult: A Study of the Spanish Group for Research on Sarcomas (GEIS)

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Abstract

Background. To explore the tolerance and the activity of high-dose ifosfamide (IFOS) combined with doxorubicin (DXR) at 50 mg/m² every 4 weeks in patients with soft tissue sarcomas. **Methods.** DXR was given IV bolus and IFOS by continuous infusion at 2 g/m²/day. Initial IFOS dose (12 g/m²) was adjusted to 10, 13, or 14 g/m² according to toxicity. **Results.** Seventy patients received 277 cycles (median 3 cycles, range 1–10), 34% with IFOS dose increased, 30% decreased, and 48% delivered at 12 g/m². Toxicity grade 4 occurred on granulocytes (67% of patients) or platelets (19%), 54% had febrile neutropenia, 31% grade 3/4 asthenia, and 26% abandoned the study due to toxicity. Three toxic deaths occurred. In 57 non-GIST patients objective activity was 45.6% (95% CI, 32 to 58%). **Conclusion.** At least 4 cycles were tolerated by 71% of patients, most receiving DXR 50 mg/m² plus IFOS 10–12 g/m², with substantial toxicity.