

Phase II study of ifosfamide + adriamycin in advanced soft tissue sarcoma in adults

A preliminary analysis

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This ongoing study includes 80 patients with previously untreated advanced soft tissue sarcoma. Other inclusion criteria are measurable progressive disease, age > 15 and < 70 years, PS < 2 , WBC ≥ 3.5 , platelets $\geq 100 \times 10^9/l$ and normal liver, kidney and cardiac function.

The treatment consisted of adriamycin 50 mg/m^2 i.v. followed by mesna 600 mg/m^2 i.v. and ifosfamide 5 g/m^2 + mesna 2.5 g/m^2 as a 24-hour infusion in 3 l dextrose saline. At the end of the infusion a further 2 l glucose saline with mesna 1.25 g/m^2 was infused over 12 h. The courses were repeated every 3 weeks.

At 15 February 1985, 33 patients were evaluable. Their median age was 49 (18–68) years and the median number of treatment courses 3 (2–7+). One complete and seven partial responses were observed, giving a response rate of 24% (10–39%) with a median duration of 3+ (2–6+) months.

Hematologic toxicity: During the first course the median WBC nadir was $2.1 \times 10^9/l$ (0.2–6.7), 48% of the patients having values below 2.0 and 18%, below 1.0. During the second course the median WBC was 2.1 (0.1–8.8) and during the third course 1.1 (0.2–3.1) $\times 10^9/l$. Thrombocytopenia of $60 \times 10^9/l$ was seen in one patient. Other toxicity: Nausea and vomiting were observed in 87%, infections in 15%, mild hematuria in 12%, oral toxicity in 11%, and diarrhea in 11%. No kidney or cardiac damage has been observed hitherto.

In conclusion, in this preliminary analysis the response rate with the combination of adriamycin and ifosfamide is encouraging and the toxicity acceptable, but longer follow up is necessary.