

This abstract was presented at the October 2001 meeting of the  
International Society of Pediatric Oncology in Australia:

Comparison of Dose Intensified and Standard Dose Chemotherapy for the Treatment non-metastatic Ewing's Sarcoma (ES) and Primitive Neuroectodermal Tumor (PNET) of Bone and Soft tissue: a Pediatric Oncology Group-Children's Cancer Group Phase III trial.  
L. Granowetter\*, R. Womer, M. Devidas, E. Perlman, R. Shamberger, M. Link, J. Neff, K. Marcus, A. Goorin, C. Arndt, P. Dickman, M. Gebhardt, H. Grier.

**Objectives:** This trial compared the outcome and toxicity of a 48 week regimen of vincristine, doxorubicin, and cyclophosphamide (VDC) alternating with Ifosfamide and Etoposide (IE), to the same agents delivered in a dose intensified 30 week regimen.

**Methods:** Between 1995-98, 492 patients were randomized. Eligibility requirements included: newly diagnosed non-metastatic ES or PNET of bone or soft tissue,  $\leq 30$  years. The total doses in mg/meter<sup>2</sup> on each regimen and planned relative dose Intensity (DI) follows:

	REGIMEN A	REGIMEN B	DI Regimen A: B
Vincristine	13.5	13.5	1: 1.6
Doxorubicin	375	375	1: 1
Cyclophosphamide	10800	12000	1: 1.8
Ifosfamide	7200	7200	1: 1.6
Etoposide	4000	3000	1: 1.2

Local control (radiation (RT), surgery, or surgery followed by RT for inadequate margins) was performed after the fifth course (week 12) of chemotherapy.

**Results:** The EFS at 3 years is 75 % (+/- 3%); 76% +/- 4% for Regimen A and 74% +/- 4% for Regimen B. The log rank tests showed no difference in EFS between the two arms (p=0.57). Mucositis and grade 4 hematologic toxicity was greater on Regimen B than Regimen A. Secondary leukemia was reported in 8 patients (4 in each regimen.) there were 5 toxic deaths on study treatment (3 Regimen A; 2 Regimen B).

**Conclusions:** The early results of this randomized trial demonstrate no significant difference in outcome between standard and dose-intensified chemotherapy. Further follow-up is required.